

Effect of pulmonary artery pressure-guided therapy on heart failure readmission in a nationally representative cohort

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Abstract

Aims Pulmonary artery pressure (PAP)-guided therapy in patients with heart failure (HF) using the CardioMEMS (CMM) device, an implantable PAP sensor, has been shown to reduce HF hospitalizations in previous studies. We sought to evaluate the clinical benefit of the CMM device in regard to 30, 90, and 180 day readmission rates in real-world usage.

Methods and results We queried the Nationwide Readmissions Database (NRD) to identify patients who underwent CMM implantation (International Classification of Diseases 9 and 10 codes) between the years 2014 and 2019 and studied their HF readmissions. Moreover, we compared CMM patients and their readmissions with a matched cohort of patients with HF but without CMM. Multivariable Cox regression analysis was performed to adjust for other predictors of readmissions. Prior to matching, we identified 5 326 530 weighted HF patients without CMM and 1842 patients with CMM. After propensity score matching for several patients and hospital-related characteristics, the cohort consisted of 1839 patients with CMM and 1924 with HF without CMM. Before matching, CMM patients were younger (67.0 ± 13.5 years vs. 72.3 ± 14.1 years, $P < 0.001$), more frequently male (62.7% vs. 51.5%, $P < 0.001$), with higher rates of prior percutaneous coronary intervention (16.9% vs. 13.2%, $P = 0.002$), peripheral vascular disease (29.6% vs. 17.8%, $P < 0.001$), pulmonary circulatory disorder (38.7% vs. 23.2%, $P < 0.001$), atrial fibrillation (51.2% vs. 45.3%, $P = 0.002$), prior left ventricular assist device (1.8% vs. 0.2%, $P < 0.001$), high income (32.2% vs. 16.4%, $P < 0.001$), and acute kidney disease (43.8% vs. 29.9%, $P < 0.001$). Readmission rates at 30 days were 17.3% vs. 20.9% for patients with vs. without CMM, respectively, and remained statistically significant after matching (17.3% vs. 21.5%, $P = 0.002$). The rates of 90 day (29.6% vs. 36.5%, $P = 0.002$) and 180 day (39.6% vs. 46.6%, $P = 0.009$) readmissions were lower in the CMM group. In a multivariable regression model, CMM was associated with lower risk of readmissions (hazard ratio 0.75, 95% confidence interval 0.63–0.89, $P = 0.001$).

Conclusions The CMM device was associated with reduced HF rehospitalization rates in a nationally representative cohort of HF patients, validating the clinical trial that led to the approval of this device and its utilization in the treatment of HF.

Keywords Pulmonary artery pressure-guided therapy; CardioMEMS device; Heart failure; Readmission

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Introduction

Despite improvements over time, heart failure (HF) remains a highly morbid and lethal disease. In addition to the conventional standard care, recent medical progress developed sev-

eral therapies, such as sacubitril-valsartan,^{1,2} inhibitors of sodium–glucose cotransporter 2 (SGLT2),^{3,4} ivabradine,⁵ and vericiguat.⁶ These medical therapies are effective and improve prognosis. However, HF patients continue to suffer high rate of rehospitalization, which significantly affects

patient's quality of life and health care cost.^{7,8} In regard to these issues, strategies to improve the rates of HF hospitalization and the efficiency of health care cost have been necessary.

The pulmonary artery (PA) implantable haemodynamic monitor is a percutaneously implanted wireless device that can measure PA pressure (PAP) in the outpatient setting, enabling more individualized and precise HF management on top of guideline-directed standard treatments for HF. In the CardioMicroelectromechanical system (CardioMEMS; CMM) Heart Sensor Allows Monitoring of Pressures to Improve Outcomes in New York Heart Association Class III Heart Failure Patients (CHAMPION) trial, PAP-guided HF management using a wireless implantable haemodynamic monitoring system (CardioMEMS HF System; St Jude Medical, Inc, Atlanta, GA) had significant short-term and long-term benefit in reducing the rates of HF hospitalization when compared with guideline-directed standard care for HF alone.^{9,10}

Herein, in the present study, we sought to investigate the national incidence, outcomes, and predictors of readmissions after CMM implantation using a nationally representative sample of patients who underwent CMM implantation.

Methods

Study database

The Nationwide Readmissions Database (NRD) was developed by the Agency for Healthcare Research and Quality's Healthcare Cost and Utilization Project. The NRD is the largest publicly available all-payer inpatient readmission database in the USA and includes all discharge records excluding long-term acute care facilities. National estimates (weighted) are available through a variable 'discwt', and the NRD contains data of 35 million weighted discharges from 28 geographically dispersed states accounting for roughly 60% of the total US population and hospitalizations. Any readmission with the status of 'non-elective' was considered unplanned readmissions. Due to the population-based retrospective nature of the study with de-identified patient records, the institutional review board approval was not required. The research reported in this paper adhered to the Helsinki Declaration as revised in 2013.

Study design and population

We conducted a retrospective cohort study of CMM implantation for HF in the USA by using the NRD. The NRD was queried to identify all patients ≥ 18 years admitted for acute HF between January 2014 and November 2019, irrespective of left ventricular ejection fraction. We divided patients into those with and without CMM implantation and we compared

the baseline characteristics, comorbidities, Elixhauser score, clinical outcomes (e.g. acute kidney injury leading to dialysis dependence and transfusion), and HF readmission rates. Patients with HF underwent CMM implantation by using the International Classification of Diseases (ICD), Tenth revision, Procedure Code System (ICD-10-PCS) code of '02HR30Z' and '02HQ30Z' and ICD, Ninth revision, Clinical Modification (ICD-9-CM) code of '3826'. Because the NRD allows tracking of readmission data for each patient within the same calendar year only, for this reason, patients admitted in December were excluded. We also excluded patients with missing data and those who died after CMM implantation. We used a validated methodology devised by Quan *et al.*¹¹ by utilizing the coding algorithms to defining the comorbidities in ICD-10 administrative data. The codes were used to calculate the Elixhauser comorbidity index. Our primary outcomes of interest were the HF readmission rate at 30, 90, and 180 days.

Statistical analysis

We performed the analysis mainly in adherence to the practice guidance for statistical and research methodologies using the NRD.¹² We excluded all the missing variables and performed a complete case analysis. Baseline characteristics, comorbidities, and hospital characteristics groups were compared using the Pearson χ^2 test and one-way ANOVA for categorical and continuous variables, as appropriate. We reported categorical variables as percentages and continuous variables as mean \pm standard deviation (SD).

We compared the baseline characteristics and comorbidities during the index admission for acute HF based on patients with and without CMM implantation. Binary outcomes (e.g. sex, comorbidities, and in-hospital complications) were modelled with binomial logistic regressions. Predictors of readmission due to HF at 30, 90, and 180 days were analysed using Cox proportional hazards regression analysis. The variables included were patient and hospital characteristics as presented in *Table 1*. Kaplan–Meier survival curves for time to readmission due to HF were calculated. A propensity score matching with 1:1 ratio was performed. The following variables were used: age, sex, hypertension, diabetes, previous myocardial infarction, previous percutaneous coronary intervention, previous coronary artery bypass graft surgery, previous permanent pacemaker implantation, chronic kidney disease, chronic obstructive pulmonary disease, peripheral vascular disease, previous stroke, pulmonary circulatory disorder, liver disease, atrial fibrillation, anaemia, cancer, previous left ventricular assist device implantation, oxygen dependence, mean Elixhauser score, hospital size, and patient income.

All data extraction and analyses were conducted using Stata 16.0 (StataCorp, 2019, Stata Statistical Software:

Table 1 Patient characteristics at baseline and outcomes at 30 days

	Before propensity score matched			After propensity score matched		
	Without CMM (n = 5 326 530)	With CMM (n = 1842)	P-value	Without CMM (n = 1942)	With CMM (n = 1839)	P-value
Age, years (SD)	72.3 (14.1)	67.0 (13.5)	<0.001	87.3%	85%	0.148
Female	48.5%	37.3%	<0.001	52.5%	51.3%	0.607
HTN	87.5%	85%	0.052	15%	15.8%	0.668
DM	46.7%	51.3%	0.025	16.7%	16.9%	0.915
Prior CABG	14.8%	15.7%	0.524	18.1%	17.4%	0.662
Prior PCI	13.2%	16.9%	0.002	6%	7.6%	0.128
Prior MI	14.7%	17.4%	0.02	55.6%	52.6%	0.335
Prior PPMI	9.6%	7.6%	0.248	39.2%	37.6%	0.496
CKD	47.2%	52.7%	0.051	29.3%	29.5%	0.938
COPD	43.6%	37.6%	0.003	11.6%	11.1%	0.729
PVD	17.8%	29.6%	<0.001	39.3%	38.7%	0.809
Prior stroke	12.8%	11.1%	0.114	5.7%	7.2%	0.194
Pulmonary circulation disorder	23.2%	38.7%	<0.001	52.2%	51.2%	0.655
Liver disease	4.7%	7.3%	0.001	8.2%	8.4%	0.848
AF	45.3%	51.2%	0.002	4.6%	4.8%	0.788
Anaemia	8.3%	8.5%	0.86	1.2%	1.8%	0.356
Cancer	4%	4.8%	0.295	8.4%	7.1%	0.331
Prior LVAD	0.2%	1.8%	<0.001	87.3%	85%	0.148
Oxygen dependence	10%	7.1%	0.018	52.5%	51.3%	0.607
Mean Elixhauser score (SD)	6.3 (2.1)	6.5 (2.3)	0.329			
Hospital bed size						
Small	18.8%	5.7%	<0.001	4.9%	5.7%	0.403
Medium	28.2%	22.6%	0.095	20.9%	22.6%	0.541
Large	53%	71.7%	<0.001	74.3%	71.7%	0.411
Household income						
Lowest	32.9%	16.7%	<0.001	16.5%	16.7%	0.923
Low-med	26.8%	22.5%	0.035	21.2%	22.5%	0.572
Med-high	22.5%	27.6%	0.002	24.8%	27.7%	0.179
High	16.4%	32.2%	<0.001	36.4%	32.2%	0.131
Mortality	2.8%	6.9%	<0.001	3.6%	7%	0.002
AKI	29.9%	43.8%	<0.001	34.7%	43.8%	<0.001
AKI leading to HD	0.9%	3.5%	<0.001	1.8%	3.5%	0.019
Transfusion	3.4%	9.8%	<0.001	3.4%	9.8%	<0.001
Stroke	0.2%	0.5%	0.041	0.2%	0.5%	0.329
Discharge			<0.001			<0.01
Routine	50.9%	50.6%		51.5	50.6	
Short-term hospital	1.0%	1.2%		1.5	1.2	
HF readmissions at 30 day follow-up	20.9%	17.3%	0.0209	21.5%	17.3%	0.0210

Abbreviations: AF, atrial fibrillation; AKI, acute kidney injury; CABG, coronary artery bypass grafting; CKD, chronic kidney disease; CMM, CardioMEMS; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; HD, haemodialysis; HF, heart failure; HTN, hypertension; LVAD, left ventricular assist device; MI, myocardial infarction; PCI, percutaneous coronary intervention; PPMI, permanent pacemaker implantation; PVD, peripheral vascular disease; SD, standard deviation.

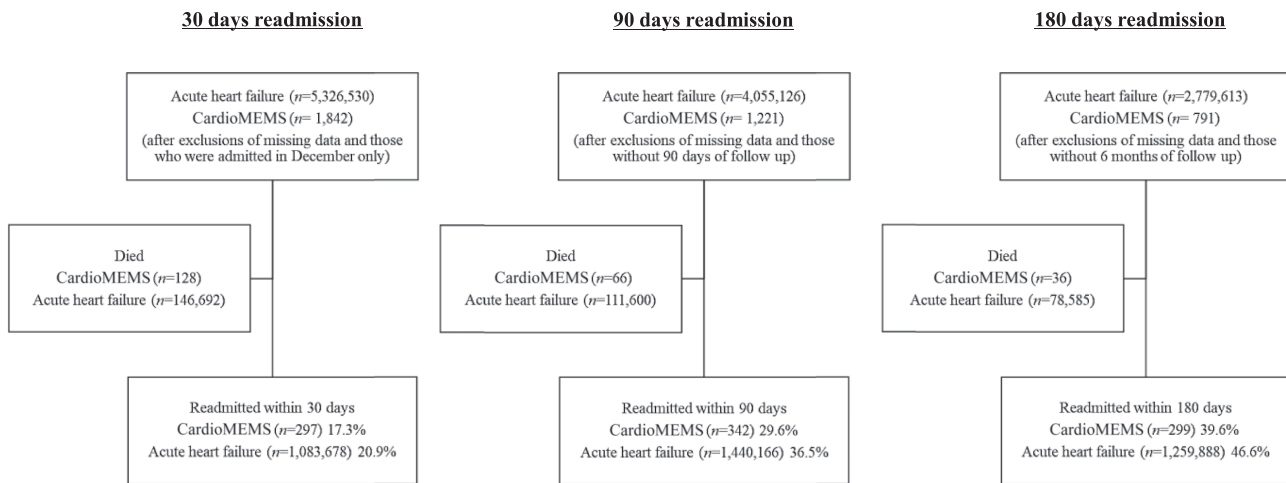
Release 16, College Station, TX: StataCorp LLC). A two-sided P-value < 0.05 was used for statistical significance.

Results

Study population

Prior to matching, we identified 5 326 530 weighted acute HF patients without CMM and 1842 patients with CMM (Figure 1). After propensity score matching for several patient and hospital-related characteristics, the cohort consisted of 1839 patients with CMM and 1924 with HF without CMM.

The comparison of baseline characteristics and clinical outcomes in patients with and without CMM are summarized in Table 1. Before matching, CMM patients were younger (67.0 ± 13.5 years vs. 72.3 ± 14.1 years, $P < 0.001$) and more frequently male (62.7% vs. 51.5%, $P < 0.001$). Before matching, CMM patients as compared with HF patients without CMM had higher rates of the following: diabetes mellitus (51.3% vs. 46.7%, $P = 0.025$), prior percutaneous coronary intervention (16.9% vs. 13.2%, $P = 0.002$), prior myocardial infarction (17.4% vs. 14.7%, $P = 0.02$), peripheral vascular disease (29.6% vs. 17.8%, $P < 0.001$), pulmonary circulatory disorder (38.7% vs. 23.2%, $P < 0.001$), liver disease (7.3% vs. 4.7%, $P = 0.001$), atrial fibrillation (51.2% vs. 45.3%, $P = 0.002$), prior left ventricular assist device

Figure 1 Study flow diagram.

(1.8% vs. 0.2%, $P < 0.001$), large hospital bed size (71.7% vs. 53%, $P < 0.001$), high income (32.2% vs. 16.4%, $P < 0.001$), and acute kidney disease (43.8% vs. 29.9%, $P < 0.001$).

Readmission rates of heart failure

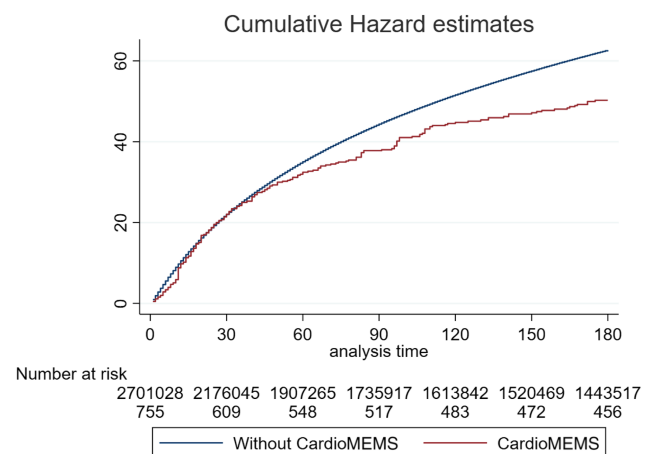
Before matching, readmission rates at 30 days were 17.3% among those with CMM vs. 20.9% among those without CMM. This difference remained statistically significant after matching (17.3% in those with CMM vs. 21.5% in those without CMM, $P = 0.02$). The rates of 90 day (29.6% vs. 36.5%, $P = 0.002$) and 180 day (39.6% vs. 46.6%, $P = 0.009$) readmissions were also lower in the CMM group (Figure 2).

Predictors for heart failure readmissions

In multivariable regression models, only CMM was associated with lower risk of readmissions at 30 days [hazard ratio (HR) 0.75, 95% confidence interval (CI) 0.63–0.89, $P = 0.001$], 90 days (HR 0.73, 95% CI 0.63–0.86, $P < 0.001$), and 180 days (HR 0.80, 95% CI 0.71–0.91, $P = 0.001$). Other independent predictors of readmission were summarized in Tables 2–4.

Other in-hospital outcomes

Our analysis showed that patients with CMM had higher in-hospital mortality (6.9% vs. 2.8%, $P < 0.001$) before matching and this difference remained significant after matching (7% vs. 3.6%, $P = 0.002$). Similarly, rates of acute kidney injury leading to haemodialysis and transfusion were

Figure 2 Cumulative incidence of heart failure readmissions during 180 days after discharge, stratified according to treatment (without or with CardioMEMS).

significantly higher in the CMM group before and after matching as shown in Table 1.

Discussion

In the present study, PAP-guided therapy in patients with HF using CMM devices was associated with reduced HF rehospitalization rates at the 30, 90, and 180 day time periods. Previous single-blind randomized control studies have shown PAP sensor implantation reduced HF hospitalization at 6 and 18 months.^{9,10} These findings are consistent with our results in a contemporary cohort of HF patients.

Table 2 Independent significant predictors of 30 day readmissions based multivariable regression analysis

	HR	95% CI	P-value
CardioMEMS	0.75	0.63–0.89	0.001
Female	1.02	1.01–1.03	<0.001
PVD	1.13	1.12–1.40	<0.001
COPD	1.19	1.18–1.20	<0.001
CKD	1.31	1.30–1.32	<0.001
Liver disease	1.24	1.22–1.25	<0.001
DM	1.10	1.09–1.10	<0.001
AF	1.11	1.10–1.12	<0.001
Prior MI	1.06	1.05–1.07	<0.001
Prior PCI	1.03	1.03–1.04	<0.001
Prior CABG	1.02	1.02–1.03	<0.001
Prior stroke	1.07	1.06–1.07	<0.001
Prior LVAD	1.16	1.10–1.23	<0.001
Anaemia	1.07	1.06–1.08	<0.001
Cancer	1.24	1.22–1.25	<0.001
Oxygen dependence	1.18	1.17–1.19	<0.001

Abbreviations: AF, atrial fibrillation; CABG, coronary artery bypass grafting; CI, confidence interval; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; HR, hazard ratio; LVAD, left ventricular assist device; MI, myocardial infarction; PCI, percutaneous coronary intervention; PVD, peripheral vascular disease.

Table 3 Independent significant predictors of 90 day readmissions based multivariable regression analysis

	HR	95% CI	P-value
CardioMEMS	0.73	0.63–0.86	<0.001
Female	1.04	1.04–1.05	<0.001
PVD	1.13	1.12–1.14	<0.001
COPD	1.19	1.18–1.19	<0.001
CKD	1.29	1.28–1.29	<0.001
Liver disease	1.18	1.17–1.20	<0.001
Rheumatoid disease	1.13	1.11–1.14	<0.001
Weight loss	1.09	1.08–1.10	<0.001
Fluid and electrolyte disturbances	1.09	1.09–1.10	<0.001
DM	1.13	1.12–1.13	<0.001
AF	1.11	1.11–1.12	<0.001
Prior MI	1.06	1.05–1.06	<0.001
Prior PCI	1.05	1.05–1.06	<0.001
Prior CABG	1.04	1.03–1.05	<0.001
Prior stroke	1.09	1.08–1.10	<0.001
Prior LVAD	1.16	1.10–1.22	<0.001
Anaemia	1.07	1.06–1.08	<0.001
Cancer	1.20	1.18–1.21	<0.001

Abbreviations: AF, atrial fibrillation; CABG, coronary artery bypass grafting; CI, confidence interval; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; HR, hazard ratio; LVAD, left ventricular assist device; MI, myocardial infarction; PCI, percutaneous coronary intervention; PVD, peripheral vascular disease.

Haemodynamic-guided HF management has also been shown effective for not only HF-related 30 day readmissions but also all-cause readmissions.¹³

Physicians and hospital administrators are now facing the difficult task of providing high-quality, proactive care for an increasing HF patient population not only to reduce the rate of costly HF hospitalizations but also to continue high-quality

Table 4 Independent significant predictors of 180 day readmissions based multivariable regression analysis

	HR	95% CI	P-value
CardioMEMS	0.80	0.71–0.91	0.001
Female	1.07	1.06–1.07	<0.001
PVD	1.13	1.12–1.13	<0.001
COPD	1.18	1.18–1.19	<0.001
CKD	1.29	1.28–1.29	<0.001
Liver disease	1.18	1.16–1.19	<0.001
DM	1.14	1.13–1.14	<0.001
AF	1.10	1.10–1.11	<0.001
Prior MI	1.06	1.06–1.07	<0.001
Prior PCI	1.06	1.06–1.07	<0.001
Prior CABG	1.04	1.03–1.04	<0.001
Prior stroke	1.09	1.09–1.10	<0.001
Prior LVAD	1.18	1.13–1.23	<0.001
Anaemia	1.07	1.06–1.08	<0.001
Cancer	1.16	1.15–1.18	<0.001
Oxygen dependence	1.18	1.17–1.19	<0.001

Abbreviations: AF, atrial fibrillation; CABG, coronary artery bypass grafting; CI, confidence interval; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; HR, hazard ratio; LVAD, left ventricular assist device; MI, myocardial infarction; PCI, percutaneous coronary intervention; PVD, peripheral vascular disease.

care during the hospitalization and extend it through 30 days after discharge. To date, currently available HF therapies and technologies have proven inadequate in solving this problem as HF hospitalizations and subsequent 30 day readmission rates remain unacceptably high.^{14–16} Intense monitoring of daily weights and symptoms failed to reduce HF hospitalizations.^{17,18} HF is cited as the most frequent principal diagnosis, resulting in over 1 million admissions per year (1–2% of all hospitalizations) in the USA.⁷ The economic impact of HF on national health care systems is profound, with the total costs of HF in the USA estimated to increase from \$31 billion in 2012 to \$70 billion in 2030, secondary to an aging population with nearly 80% of costs attributed to hospitalizations alone.⁸

Treating HF symptoms once they are reported often fails to prevent admission to the hospital. With the premise that HF patients develop increased filling pressures days to weeks before symptomatic worsening or weight change, an ideal technology would allow a window of treatment to course correct these decompensations and avoid the need for hospitalization. The proof of concept was demonstrated in the CHAMPION trial where continuous monitoring of PAPs with up-titration and adjustment of vasodilators and diuretics, reduced HF readmissions and improved quality of life. CMM offered benefits at a cost below the commonly accepted US willingness-to-pay thresholds compared with usual care alone, assuming the trial effectiveness is sustained over longer periods. Furthermore, the device was also cost-effective for functional class III patients with both reduced ejection fraction and preserved ejection fraction.¹⁹

Patient's baseline characteristics in this study showed resemblance to those in previous trials.^{9,10,20,21} For example, age, sex, and proportion of comorbidities, including diabetes, chronic obstructive pulmonary disease, and atrial fibrillation, are similar, whereas chronic kidney disease and previous left ventricular assist device implantation are more frequent, and ischaemic heart disease is less frequent in this study. Additionally, the observed treatment effect in this study was similar to that observed in previous trials.^{9,10,21–25} The observed risk reduction in HF hospitalizations was similar to the 20–30% decrease reported for patients with New York Heart Association (NYHA) functional class III HF and a previous HF hospitalization in the CHAMPION trial^{9,10} and those with NYHA functional class II–IV HF and either a previous HF hospitalization or elevated natriuretic peptides in the Haemodynamic-GUIDEed management of Heart Failure (GUIDE-HF) trial.²⁰ This finding was also consistent with the reports of other observational studies, including the CardioMEMS US Post-Approval Study,²¹ and clinical trials reporting the benefits of haemodynamic guided monitoring.²² Moreover, in the multivariable regression analysis, the risk reduction effect of readmission with CMM directed medical therapy was constant at 30, 90, and 180 days (HR 0.75, 95% CI 0.63–0.89, $P = 0.001$; HR 0.73, 95% CI 0.63–0.86, $P < 0.001$; and HR 0.80, 95% CI 0.71–0.91, $P = 0.001$). These results support the efficacy of CMM devices for the prevention of HF hospitalization and cost-effectiveness in clinical practice settings and demonstrated that this implantable haemodynamic monitoring device strategy can be broadly applied to improve hospitalization rates in routine clinical practice. The signal for higher risk of in-hospital complications such as in-hospital mortality and acute kidney injury requiring haemodialysis likely represents higher burden of comorbidities and perhaps more advanced HF stage among CMM recipients. Despite implementation of propensity match scoring, confounding and selection bias cannot be completely eliminated. A plausible hypothesis is that patients followed at specialized HF programmes are more likely to be referred for advanced symptoms and these could be candidates for CMM as a measure to decrease readmission, achieve euvoelaemia, and scrutinize guideline-directed medical therapy. Furthermore, disparities in access to CMM technology should be addressed. Most patients with CMM were in larger bed-size hospitals and it is possible that candidates for this remote

monitoring strategy may not have access to it if they receive their care in smaller rural non-tertiary hospitals.

There are several limitations to our study. First, NRD utilizes data primarily collected for billing purpose using ICD 9 and 10 codes; therefore, there is a risk of miscoding diagnoses and clinical events and we cannot ignore the potential impact on our analysis. Second, due to the retrospective nature of NRD, although we performed multivariate Cox regression model for identifying predictors of readmissions, the potential for residual confounders cannot be excluded. Third, we identified a large number of missing values in the variables of gender and ethnicity; hence, we did not perform subgroup analyses for these parameters. Finally, granular data such as left ventricular ejection fraction, cardiopulmonary exercise testing, resting haemodynamics, and medical therapies prescribed are not available in this database. The main strength of our analysis is the use of a nationally representative readmission sample and the comprehensive evaluation of trends, causes, and outcomes related to these conditions.

In conclusion, PAP-guided therapy in patients with HF using CMM was associated with lower risk of HF rehospitalization at 30, 90, and 180 days in a nationally representative cohort of HF patients. This is particularly important given the morbidity and health care resource utilization related to readmissions.

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Conflict of interest

None declared.

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