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Assessing the Impact of Hemodynamic Monitoring with CardioMEMS on Heart Failure Patients: A Cost-Benefit Analysis

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Abstract: Aims: The objective of this study was to assess the cost-effectiveness of the CardioMEMS HF system in a HF Clinic in Spain by evaluating the real-time remote monitoring of pulmonary artery pressures, which has shown to reduce heart failure (HF) related hospitalizations and improve the quality of life for selected HF patients. Particularly, the study aimed to determine the value of CardioMEMS in Southern Europe, where healthcare costs are significantly lower and its effectiveness remains uncertain. **Methods**: This single-centre study enrolled all consecutive HF patients who had been implanted with a pulmonary artery pressure sensor (CardioMEMS-HF system, Abbott Laboratories, Abbott Park, IL, USA). The number of HF hospitalizations in the year before and the year after the sensor implantation was compared and quality-adjusted life years (QALY) gained based on a literature review of previous studies was calculated. **Results**: The rate of HF hospitalisations was significantly lower at 1 year compared with the year before CardioMEMS implantation (0.25 versus 1.10 events/patient-years, HR 0.22, p=0.001). At the end of first year, the usual management outperformed the CardioMEMS HF system, resulting in a net monetary value difference of 2,540€ per patient and a benefit-cost ratio of 0.38. However, by the end of the second year, the CardioMEMS system is estimated to reduce costs compared to usual management. **Conclusions**: Based on the results, we suggest that remote monitoring of pulmonary artery pressure with the CardioMEMS HF system represents a long-term cost-effective strategy in a healthcare setting in Southern Europe.

Keywords: cost-effectiveness evaluation; heart failure; telemonitoring; pulmonary artery pressure; hemodynamic monitoring

INTRODUCTION

Heart failure (HF) is a major public health problem and a leading cause of hospitalisation in Western countries. The prevalence of HF is approximately 2% in the adult population in Spain, rising to ≥10% among people >80 years of age.[1] The most common cause of hospitalisation in HF patients is HF decompensation, which leads to a progressive deterioration of myocardial function and quality of life and also represents the most important determinant of HF associated costs in our country. [2]

Despite improvements in HF therapy, the 12-month hospitalisation rates remain very high in this population, ranging from 32% to 44% for ambulatory and hospitalised patients, respectively.[3]

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Remote monitoring emerged as a viable way to overcome the long interval between office visits and to keep patients safe by identifying disease progression in time to prevent hospitalisation.[4] The CardioMEMS HF System (St. Jude Medical, Inc., Atlanta, GA, USA) is the first system to provide real-time remote monitoring of pulmonary artery pressures (PAP), with the goal of maintaining this pressure within a therapeutic range by adjusting medications in response to pressure trends. Unlike other implantable devices, the CardioMEMS pressure sensor does not require a battery and therefore, continues to function indefinitely.

In a randomised controlled trial of 550 New York Heart Association (NYHA) class III HF patients with a previous HF hospitalisation, those whose treatment was guided by PAP measurements (treatment group) achieved a 33% reduction in HF-related hospitalisations over an average study duration of 15 months compared with the control arm, who had the device implanted but in whom the data were not used to guide management. The treatment group also had a higher reduction in mean PAP and a greater improvement in quality of life.[5]

In 2014 CardioMEMS was approved for use in the United States of America by the Food and Drug Administration and in 2016 the Heart Failure Association of the European Society of Cardiology (ESC) included the system in the ESC guidelines for the diagnosis and treatment of acute and chronic HF, indicating that the device may be considered for monitoring symptomatic patients with a previous HF hospitalisation in order to reduce the risk of recurrent hospitalisation (class IIb recommendation, level of evidence B).[6]

A randomised controlled trial conducted in the Netherlands has recently confirmed that haemodynamic monitoring of pulmonary pressures improves quality of life and reduces HF hospitalisations and a previous cost-utility analysis suggested that the CardioMEMS HF system is also a cost-effective strategy for HF patients in the United Kingdom.[7,8] However, the value of CardioMEMS in Southern Europe, where hospitalizations costs are significantly lower, remains uncertain and this might lead to an underutilization of the device. The aim of this study was to estimate the cost and benefits of CardioMEMS in a healthcare centre from Spain.

METHODS

Study population and follow-up

The study was carried out in a HF clinic of a tertiary hospital in the Northern area of Barcelona. This hospital was a pioneer in the use of pulmonary pressure sensors in southern Europe and currently follows the largest number of patients with the CardioMEMS device implanted in the country.

All consecutive patients implanted with a CardioMEMS from June 2019 to November 2021 were included in the analysis.

The criteria for implementing the CardioMEMS HF System were the presence of symptomatic HF with a high risk of HF hospitalisation, regardless of the ejection fraction, in patients already receiving optimal medical treatment.

Since patients initiated follow-up at the HF Clinic, they were followed in regular follow-up visits, including a minimum of one visit with a nurse every 3 months and one visit with a physician (cardiologist or internist) every 6 months.

After CardioMEMS implantation, a range of optimal values of PAP was established considering the pulmonary capillary wedge pressure and the transpulmonary gradient of each patient. These PAP thresholds were adjusted during the first week of follow-up. Subsequently, the HF specialist nurses reviewed the PAP values daily and when the established range was exceeded, the cardiologist assessed the possibility of adjusting the diuretic or vasodilator treatment.

During the baseline visit, patients provided written consent for the use of their clinical data for research purposes. Demographic, clinical, echocardiographic, and analytical data were recorded in a specific database (Ethical Committee number PI-18-037).

To conduct the cost-benefit analysis, annualised HF hospitalisations in the year before and the year after sensor implantation were taken into account, considering time at risk for each patient.

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Additional calculations were made in order to assess the accumulated costs over five years; for those calculations, a 3% discount rate was considered as per the recommendations for health economics in the Spanish healthcare system.[9]

The study was performed in compliance with the laws that protect personal data, in accordance with the international guidelines on clinical investigations from the World Medical Association's Declaration of Helsinki.

Resources and costs

The costs assessed in the study were chosen based on the description of costs from previous studies. To do so, a literature review of CardioMEMS cost-effectiveness analysis (ranging from 2011 to 2021) was conducted. Out of eleven results yielded, only six were actual economic evaluations. As shown in Supplementary Table 1, four of the six research papers found were conducted in the United States of America, one in different countries of the European Union (United Kingdom, the Netherlands, Belgium, Italy and Germany) and one in Argentina. The mean and median Incremental Cost-Effectiveness Ratio (ICER), converting currency and adjusting for inflation, were of €34,432 and €23,236 respectively; as for the QALY gained after the implant of the CardioMEMS device, the mean and median values were 0.42 and 0.39 respectively.[5,8,10–13]

Table 1. Cost and resources description.

Parameter	Cost	Source(s)
CardioMems HF device (each)	€11.440	Own
Pillow (each)	€1.210	Own
Implant procedure	€1.528	[14]
Outpatient costs		
Monitoring by the nurse (30' daily, five days a week)	€16,31	[19]
Regular visits with the nurse (Every 4 months)	€80	[14]
Regular visits with the cardiologist (Every 6 months)	€80	[14]
Hospitalisation (per day)	€674	[14]

The perspective of the evaluation was conducted from the hospital centre in order to estimate the costs and impact of the CardioMEMS treatment in comparison to standard treatment.

Table 1 shows a valuation of the costs and resources. The cost of the device and its pillow, including taxes, totalled €12,650. The implant procedure totalled €1,528, counting the use and costs derived from the haemodynamics room (including the salary of the interventional cardiologist), according to public prices.[14] Outpatient costs, including monitoring, regular visits and possible hospitalisations were taken into account. Monitoring costs were accounted for as a nurse's 30-minute salary, which is the daily time a nurse needs to consult the pulmonary pressures of CardioMEMS patients (this process is repeated 5 days a week). Such cost is accounted as €63 per patient per year, given the fact all patients are covered under that time.

Regular visits were appointed both with the HF Cardiologist (every 6 months) and the nurse (every 3 months). Both regular appointments were accounted for as an outpatient visit under public prices at €80 per visit.[14,15]

The hospitalisation per day price is an average of €674. No hospital admission costs were accounted for CardioMEMS implantation as patients were discharged on the same day of implantation.

We valuated the QALY at €25,000.[16-17] An effectiveness of 0,3 QALY was taken as reference as according to the CHAMPION trial.[5]

The costs, resources and benefits of the study and its evaluation were valued in euros (€) as of 2022. The currencies were converted to 2022 euros per the price dates in each study. The reporting of

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this study follows the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) framework for economic evaluations.[18]

Statistical analysis

Categorical variables are expressed as absolute numbers and percentages. Continuous variables are expressed as the mean ± standard deviation for normal distributions, or the median and interquartile range, for non-normal distribution. Normal distributions were assessed with normal Quantile-Quantile plots. Comparisons between groups were performed with paired t-test for continuous variables.

To compute the HF hospitalisation rate for pre- and post-sensor implantation, the risk exposure time (total follow-up time until death, minus days of hospitalisation) for each patient was taken into account. For the cost analysis, both the number of hospital admissions and the length of stay were taken into account.

RESULTS

From September 2019 to November 2021, 43 patients from the same HF clinic had a CardioMEMS device implanted, with a balanced representation of both male and female participants, aged 75.5±7.0 years, with both reduced and preserved left ventricular ejection fraction (mean LVEF 49±14%). 67.4% of them were in New York Heart Association (NYHA) class III and 32.6% in NYHA class II. Mean creatinine was 1.37±0.49mg/dL and median baseline NT-ProBNP 1919 pg/mL [IQR 1014-3339].

79,1% had been previously admitted due to HF decompensation at least once during the year before CardioMEMS implantation (53.5% two or more times). 7 patients died during the first year of follow-up (two of them due to cardiovascular causes, none of them due to HF), mean follow-up for those patients was 208.9±91.3 days. The final patient completed 1-year follow-up in November 2022.

Baseline demographics, clinical characteristics, and treatments of the included patients are shown in Table 2.

Table 2. Baseline demographic and clinical characteristics.

	CardioMEMS patients (n=43)
Age (years)	75.5.1±7.0
Male	22 (51.2)
BMI (Kg/m^2)	29.0±5.4
LVEF (%)	48.7±13.8
NYHA class II III	 14 (32.6) 29 (67.4)
Ischaemic aetiology	13 (30.2)
Hypertension	36 (83.7)
Dyslipidemia	34 (79.0)
Diabetes mellitus	18 (41.9)
Atrial fibrillation	28 (65.1)
COPD	9 (20.9)

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Anaemia[#]	23 (53.5)
Serum creatinine (mg/dl)	1.37±0.49
Baseline HF medication	
Loop diuretic	40 (93.0)
ACEI/ARB/ARNI	30 (69.8)
Beta-blocker	31 (72.1)
SGLT2i	3 (7.0)
Digitalis	10 (23.3)
Hydralazine	13 (30.2)
MRA	33 (76.7)
NT-proBNP (pg/ml)	1919 [1014-3339]
ICD	8 (18.6)
CRT	7 (16.3)

Data in mean ± SD, median (IQR) or n (%). [#]According to W.H.O. criteria (<13 g/dl in men and <12 g/dl in women). ACEI: angiotensin converting enzyme inhibitor; ARB: angiotensin II receptor blocker; ARNI: angiotensin receptor and neprilysin inhibitor; BMI: body mass index; COPD: chronic obstructive pulmonary disease; CRT: cardiac resynchronization therapy; HF: heart failure; ICD: implantable cardiac defibrillator; LVEF: left ventricular ejection fraction; MRA: mineralocorticoid receptor antagonist; NYHA: New York Heart Association; NT-proBNP: N-terminal pro-B-type natriuretic peptide; SGLT2i: sodium-glucose co-transporter-2 inhibitors.

The rate of HF hospitalisations was significantly lower at 1 year compared with the year before CardioMEMS implantation (0.25 versus 1.10 events/patient-years, HR 0.22, P=0.001), with an absolute reduction of 0.85 events/patient-years. Figure 1.

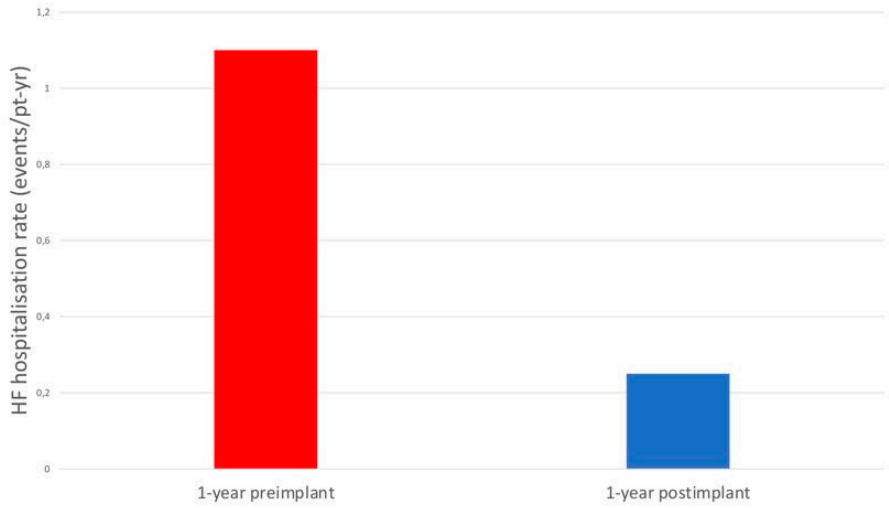

Figure 1. Heart failure hospitalisation rates.

Hospital admissions were considerably longer for the post-CardioMEMS period (30.5 days) in comparison with the pre-CardioMEMS period (12.53 days). Table 3 shows the comparison between costs and benefits for patients before and after having the CardioMEMS HF System for the first year. For the post-treatment group, the device and its implant account for the majority of the costs, while in the pre-treatment group the hospitalisation costs comprised most of the costs. As for the outpatient

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costs, both groups had regular appointments with nurses and the cardiologist. The benefit-cost ratio was €7,500/€19,688 for the post-treatment group at 1 year.

Table 3. Cost and benefits for patients before and after CardioMEMS, first year.

		Costs and benefits per patient			
		Post-CM	%	Pre-CM	%
CardioMEMS	Device	€11.440	58,1%	€0	0%
	Pillow	€1.210	6%	€0	0%
	Implant procedure	€1.528	8%	€0	0%
Total device cost		€14.178	72,01%	€0	0%
Outpatient costs	Montioring	€63	0,32%	€0	0,00%
	Nurse	€240	1,22%	€240	2,49%
	Cardiologist	€160	0,81%	€160	1,66%
Total outpatient cost		€463	2,35%	€400	4,15%
	Hospitalisation	€5.047	25,63%	€9.248	95,85%
Total costs		€19.688	100,00%	€9.648	100,00%
Benefits	QALY	€7.500		€0	
	Monetary value	€12.188		€9.648	

QALY: Quality-Adjusted Life Years.

Considering the QALY gained (applied by the beginning of the first year of the study) as a benefit, a constant cost of hospitalisation for all groups and a 3% discount rate, the initial costs are higher for the post-CardioMEMS group due to the high costs of the device, however they are rapidly outgrown by the costs of the pre-CardioMEMS period, which are mainly driven by higher hospitalisation costs, as shown in Figure 2. By the end of year 2, the costs of the post-CardioMEMS and pre-CardioMEMS groups would be of €18,435 and €17,207, with a reduction in accumulated costs of €1,228 in favour of the post-CardioMEMS group. By the end of year 5, the accumulated estimated costs for the post-CardioMEMS and pre-CardioMEMS groups would be of €31.846 and €44.066, respectively. (Figure 3). Several sensitivity analyses were performed in order to evaluate how the results could be affected by changes in key assumptions or variables (Supplementary tables 2 and 3).

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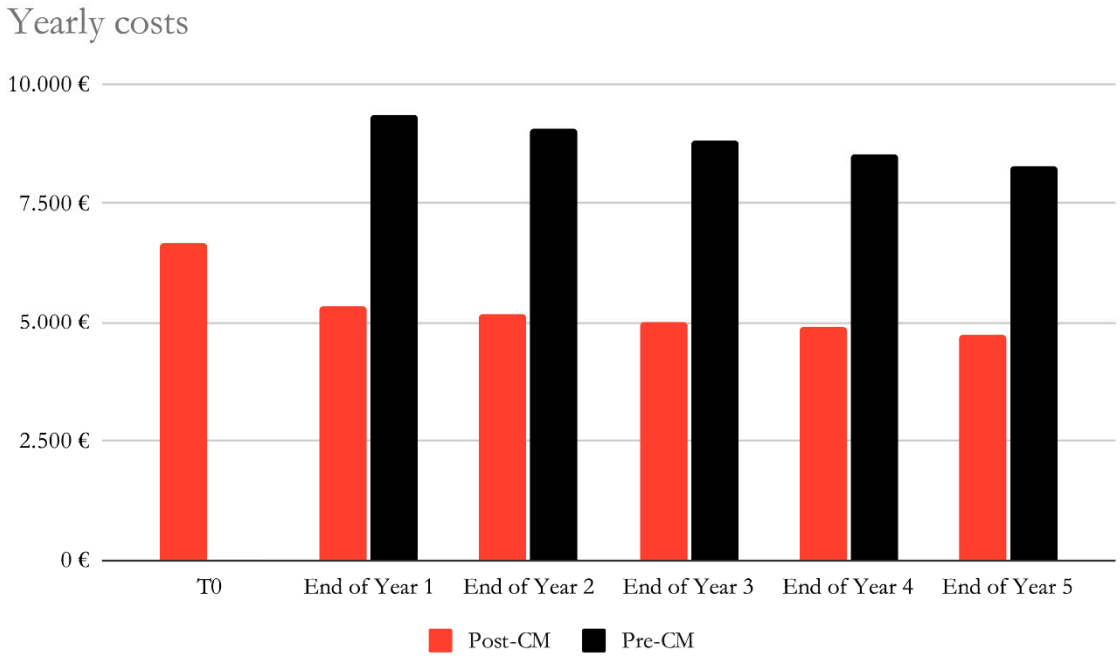

Figure 2. Cost evolution over 5 years. Considering the QALY gained as a benefit, a constant cost of hospitalisation for all groups and a 3% discount rate. Pre-CM: Pre CardioMEMS period; Post-CM: Post cardioMEMS period; T0: after CardioMEMS implantation.

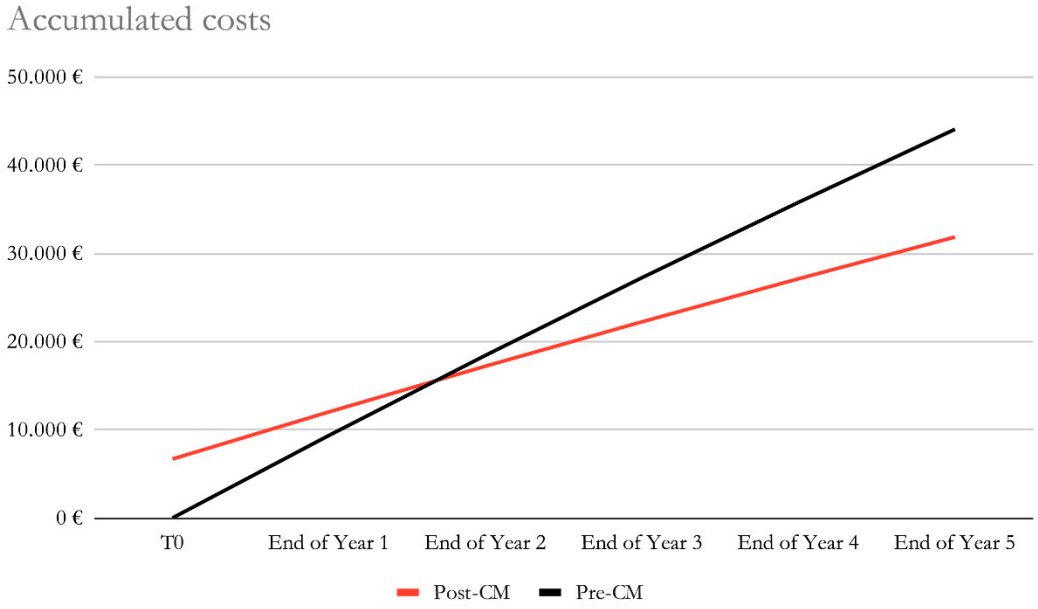

Figure 3. Accumulated estimated costs over 5 years. Considering the QALY gained as a benefit, a constant cost of hospitalisation for all groups and a 3% discount rate. Pre-CM: Pre CardioMEMS period; Post-CM: Post cardioMEMS period.

DISCUSSION

To our knowledge, this is the first study to perform a cost-benefit analysis of the CardioMEMS system in a HF clinic from Southern Europe. Remote monitoring of PAP with CardioMEMS was associated with a strong reduction in HF hospitalisations at 1 year.

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Hospitalisation costs in Spain are lower in relation to the United Kingdom and the United States of America. Therefore, one could think the potential savings by avoiding HF admissions with remote PAP monitoring are also lower. This belief currently leads to an underutilization of this invasive remote monitoring strategy in Southern Europe in comparison to other countries.

In this study, considering the QALY gained as a benefit, a constant cost of hospitalisation for all groups and a 3% discount rate, the initial costs are higher for the post-CardioMEMS group due to the high costs of the device, however they are rapidly outgrown by the costs of the pre-CardioMEMS period, which are mainly driven by higher hospitalisation costs (Figure 2).

Hospital admissions for the post-CardioMEMS period were considerably longer than those of the pre-CardioMEMS and matched control groups. A possible explanation is that patients who are admitted despite hemodynamic-guided treatment are more complex and require longer admissions.

The fact that the CardioMEMS system requires no batteries or replacements, along with patients having a lifespan exceeding two years, makes invasive remote monitoring not only a more effective but also a more cost-effective long-term strategy.

Table 4 shows the cost structure along that of the six other studies conducted since the CHAMPION trial. The actual cost shown in this article is similar to the studies by Schmier et al., Cowie et al. and Alcaraz et al., all published after 2017 and all very similar in their cost structure: device, implantation, complications, monitoring, usual cost of heart failure treatment and possible hospitalisations. This work has considered all these costs except for complications (due to their small number in our cohort, as only one patient had a vascular complication) and introduced costs related to regular visits with the nurse and HF cardiologist. Regarding the valuation of costs, ours were most similar to those described in Cowie et al, probably due to a similar context in terms of healthcare.

Table 4. Cost structure of the studies found in the literature.

Abraham et al. [5]	Sandhu et al. [10]	Martinson et al. [11]	Schmier et al. [12]	Cowie et al. [8]	Alcaraz et al. [13]	Present study
Device	Device	Refers to a market analysis and only presents accumulated costs, not disaggregated	Device	Device	Device	Device
Implant			Implant	Implant	Implant	Implant
			Complications	Complications	Complications	
	Monitoring (nurse wages)		Monitoring (nurse wages)	Monitoring (nurse wages)	Monitoring (nurse wages)	Monitoring (nurse wages)
						Regular visits
			Usual care for HF patients	Usual care for HF patients	Usual care for HF patients	Usual care for HF patients
Hospitalisation	Hospitalisation		Hospitalisation	Hospitalisation	Hospitalisation	Hospitalisation
Drugs						
End of life support						

The CHAMPION trial found that the CardioMEMS implant had a benefit of 0.3 QALY for the patient; we used it as an effectiveness benchmark for our study. However, it could be considered a low-range benefit compared to the mean and median of other published articles, at a benefit of 0,42 and 0,39 QALY respectively (supplementary table 1). This could mean that the actual benefit is higher than what we have considered, making the benefit-cost ratio higher.

Study limitations

These results should be interpreted in the context of several potential limitations. First, despite having more implants than any other healthcare centre in Southern Europe and being responsible for over half of the implants performed in Spain, the sample is limited and from a single centre. Of note, a common follow-up protocol with the HF nurse and doctor was applied to all patients during the whole study period, limiting possible bias introduced by different management strategies.

Second, the relative reduction in HF hospitalisations in post-CardioMEMS period was greater than that observed in the CHAMPION trial, but similar to other more recent reports.[19] Finally, a potential limitation lies in the fact that the sensor's effectiveness depends on the quality of the existing HF unit. If a HF Unit is already very efficient at preventing HF admissions using other remote non-invasive strategies, the CardioMEMS system may not be as effective.

CONCLUSIONS

The findings from this analysis strongly support the utilisation of remote monitoring of PAP with the CardioMEMS HF system as a cost-effective, long-term strategy within healthcare centres in Southern Europe. Given the considerable benefits observed in terms of prevention of HF admissions, the CardioMEMS system emerges as a superior alternative to usual management for selected patients at high risk of HF hospitalisation.

Supplementary Materials: The following supporting information can be downloaded at the website of this paper posted on Preprints.org.

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