# Use of CardioMEMs HF Sensor in Management of NYHA Class III Heart Failure

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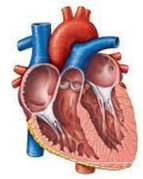
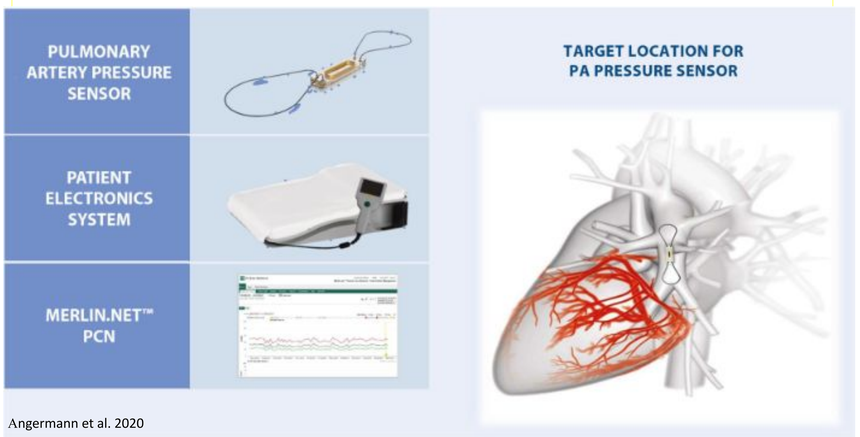


## INTRODUCTION

Heart failure is a chronic condition characterized by a compromised ability of the heart to maintain sufficient cardiac output. The severity of heart failure is broken into NYHA classes I-IV. Classes III and IV are associated with markedly higher rates of acute exacerbation requiring emergent medical attention.

Heart failure patients are conventionally managed through outpatient cardiologists with treatment dictated by physical exam, laboratory studies, and echocardiography. Interventions are made in response to changes in presentation, which are closely associated with worsening of disease. Despite well-established outpatient treatment strategies, the condition is associated with frequent hospitalization and acute exacerbation. In 2014, primary heart failure resulted in 1.1 million emergency department visits, 980,000 hospitalizations, and 80,000 deaths. The data is suggestive of a medical climate in which progression to Class IV heart failure is an inevitability rather than a potential outcome.

With advancements in modern technology, real time adjustments to patient care regimens are now implementable prior to disease worsening. One of these strategies involves a permanent implantable device that measures and transmits pulmonary artery filling pressures to the patient's cardiologist. This allows for proactive management of heart failure with the goal of stabilizing symptoms and avoiding the inevitable descent into Class IV status. The CardioMEMS HF sensor is a device indicated for Class III heart failure patients, approved by the FDA in 2014, but has yet to be widely adopted.

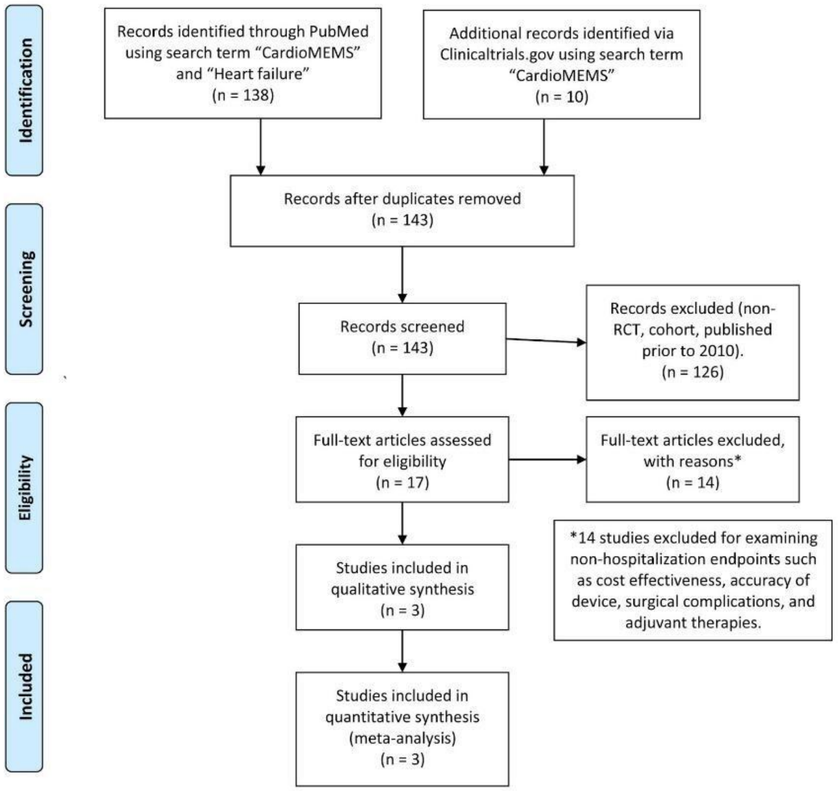



Angermann et al. 2020

## OBJECTIVES

The aims of this study are to perform a systematic literature review to assess the efficacy of using real time monitoring through the CardioMEMS implantable device in improving patient outcomes. Outcomes to be assessed include frequency of exacerbation and mortality.

## METHODS




## RESULTS

| Publication | % Reduction in HF-Related Hospitalizations | 95% Confidence interval | p-values |
|---|---|---|---|
| **Abraham 2011** | 28% | 0.60-0.85 | 0.0002 |
| **Abraham 2016** | 48% | 0.40-0.80 | <0.0001 |
| **Angermann 2020** | 62% | 0.31-0.48 | <0.0001 |

Table 1: Summary of primary endpoints across each of the included studies

| Publication | Secondary Endpoint | Secondary Endpoint |
|---|---|---|
| **Abraham 2011** | 21% Decrease in all cause hospitalization | - |
| **Abraham 2016** | 47% Decrease in death or hospitalization due to HF | 16.8% Improvement in perceived quality of life |
| **Angermann 2020** | 100% Decrease in hospitalization due to HF after 6 months | 35.5% of participants improved to NYHA Class II HF |

Table 2: Summary of secondary endpoints across each of the included studies

## DISCUSSION

- All three studies reviewed unanimously support the efficacy of the CardioMEMs HF sensor in the management of NYHA Class III heart failure when compared to conventional management.
- In Angermann 2020, the majority of patients that underwent heart failure related hospitalization took place during the first six months of the trial, suggesting that patient outcomes improved with time, this is further supported by the 35.5% of trial participants that improved from Class III to Class II by the end of the 12 month monitoring period.
- Findings in the Minnesota Living with Heart Failure Questionnaire were significant for a perceived better quality of life, less likely to get seriously ill, and experience exacerbations for a shorter amount of time.
- Limitations to this analysis and the implementation of the CardioMEMs HF in heart failure management are the low number of randomized control trials and the authors association with the biotechnology company that owns the patent for the device.
- Emerging trends in healthcare highlight the need for telehealth care and the ability to manage patients with serious conditions outside of inpatient units

## CONCLUSIONS

The CardioMEMs HF device is a safe and effective method of gathering the data necessary to proactively modify the treatment of NYHA Class III heart failure preventing disease advancement and subsequently reduce overall heart failure related hospitalizations, even reversing it to NYHA Class II in certain populations.

The wireless and remote nature of the technology allow it to be integrated into a framework of rural health and telemedicine, enabling patients to receive a high standard of care without the burden of frequent travel to and from medical centers.

Questions remain about the longevity of the CardioMEMs HF device and its continued efficacy in heart failure management, but there are 20 in-process clinical trials that may help clarify many of these concerns.

## ACKNOWLEDGEMENTS

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