



## Remote pulmonary artery pressure monitoring in heart failure care: part of the new normal?

Individuals with heart failure experience debilitating symptoms, compromised functional status, and poor quality of life. Worldwide, hospital admissions for worsening heart failure constitute an enormous burden at the societal, economic, and health-care levels. This burden highlights a crucial unmet need for effective strategies to improve outcomes.

Remote haemodynamic monitoring has been assessed over the past two decades with the aim of detecting imminent cardiac decompensation.<sup>1</sup> An increase in pulmonary artery pressure is an early indicator of haemodynamic congestion. Two landmark trials, CHAMPION<sup>2</sup> and GUIDE-HF<sup>3</sup> showed the feasibility and efficacy of the CardioMEMS-HF system (Abbott Laboratories, Abbott Park, IL, USA) technology for monitoring pulmonary artery pressure. Although GUIDE-HF was neutral overall, a prespecified pre-COVID-19 impact analysis suggested significant benefit (24% reduction in heart failure events after 12 months) from pulmonary artery pressure monitoring, which in 2022 prompted expanded US Food and Drug Administration approval for use of the CardioMEMS-HF system in individuals fulfilling GUIDE-HF inclusion criteria.<sup>3</sup>

The MONITOR-HF study, reported by Jasper Brugts and colleagues in *The Lancet*,<sup>4</sup> is the first randomised trial outside of the USA to investigate the effects of haemodynamic-guided remote patient management with individualised adjustment of guideline-directed medical therapies (GDMT). The primary outcome was the between-group difference in the Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary score. 348 individuals with heart failure who, as CHAMPION participants,<sup>2</sup> had New York Heart Association class III symptoms and at least one heart failure-related hospitalisation in the preceding year, were randomly assigned, irrespective of ejection fraction, to undergo pulmonary artery pressure-guided remote patient management after implantation of a CardioMEMS-HF device in addition to standard care, or be managed using standard care only. The median age of the participants was 69 years (IQR 61–75), 263 (76%) were men, 85 (24%) were women, and the median ejection fraction was 30%.

MONITOR-HF was the first randomised study to show that haemodynamic-guided remote patient management might improve quality of life and reduce heart failure events in this population.<sup>4</sup> The between-group difference in 12-month KCCQ overall score changes was 7.13 (95% CI 1.51–12.75;  $p=0.013$ ), with a change from baseline of +7.05 in the pulmonary artery pressure monitoring group ( $p=0.0014$ ) and  $-0.08$  in the standard care group ( $p=0.97$ ).<sup>4</sup> During 1.8 years (SD 0.9) of follow-up, pulmonary artery pressure monitoring reduced total heart failure-related hospitalisations by 44% compared with standard care (hazard ratio 0.56 [95% CI 0.38–0.84;  $p=0.0053$ ; 117 vs 212 events]).<sup>4</sup>

Whereas CHAMPION and GUIDE-HF used a double-blind, implanted control design,<sup>2,3</sup> MONITOR-HF was open-label, unblinded, and had a non-implanted control group.<sup>4</sup> This design has inherent limitations because placebo effects could have differentially affected KCCQ score changes in both study groups. Reassuringly, concomitant pronounced reductions in mean pulmonary artery pressure ( $-8.4$  mm Hg;  $p<0.0001$ ) and median NT-proBNP ( $-669$  pg/mL;  $p=0.013$ ), versus no significant changes in controls corroborated the improvements in health status.<sup>4</sup> Another limitation is that the trial was not powered for between-group comparison of mortality rates. A larger sample size, longer follow-up period, or a combination of the two

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would have been required for mortality benefits to become apparent. Lastly, MONITOR-HF results were obtained within Dutch health-care structures, and replicability in other European settings with regulatory agencies dictating different approaches to standard care for patients with heart failure awaits confirmation.<sup>5</sup>

Despite these limitations, the consistency of outcomes across the three trials is remarkable, even though they were done in different eras, under different conditions (including during the COVID-19 pandemic), in diverse health-care settings, and with evolving GDMT. The different trial designs complement each other. Observations from post-market studies,<sup>1,6-8</sup> extend the level of aggregated evidence for the benefits of haemodynamic-guided remote patient management. For example, analyses from MEMS-HF suggested a possible link between depressive symptoms and haemodynamic congestion,<sup>7</sup> and indicated that participants benefited from pulmonary artery pressure-guided remote patient management irrespective of presence or subtype of pulmonary hypertension at baseline.<sup>8</sup> Together, findings provide robust information for health-care providers, regulatory agencies, and payers about the potential of pulmonary artery pressure-guided heart failure management.

MONITOR-HF showed substantial benefits in patients discharged after a heart failure-related hospitalisation when pulmonary artery pressure monitoring was used by a multidisciplinary team involving specialised nurses and cardiologists in a high-quality structured standard-care setting. To reproduce these results on a large scale in real-life health care, diligent patient selection should identify those at high risk of heart failure-related hospitalisation who agree with the concept of daily data collection and are able and motivated to comply with treatment recommendations even if asymptomatic. Without direct interaction between health-care providers and patients, and timely treatment modification triggered by abnormal monitoring results, the care cycle might break and the potential benefits from early detection of decompensation would be lost.<sup>9</sup> Shared decisions about monitoring tools and treatment goals, patient empowerment, and compliance with GDMT are required for longer-term outcome improvements.<sup>10</sup>

Scientific evidence supports the use of the CardioMEMS-HF system to enhance remote patient management in heart failure care. For more widespread

application technological advancements are desirable to provide more comfort for patients and re-usable external device components, thereby improving care experience and saving resources. Algorithms for how to integrate this and other remote patient management strategies into care logistics and country-specific reimbursement strategies must be developed, but are still in their infancy. Furthermore, data access and security and increasing use of artificial intelligence to support analysis and interpretation are pivotal to optimal usage of pulmonary artery pressure monitoring.<sup>1,11</sup> Our greatest challenge remains to ensure that we provide optimal care tailored to patients' individual needs, considering social circumstances, digital literacy, cognitive abilities, and social and health environments.

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