Heart, Lung and Circulation (2019) **28,** e47–e50
1443-9506/04/$36.00
https://doi.org/10.1016/j.hlc.2018.03.025

BRIEF COMMUNICATION

Trends in the Utilisation and In-Hospital Mortality Associated With Short-Term Mechanical Circulatory Support for Heart Failure With Reduced Ejection Fraction

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Received 6 February 2018; received in revised form 12 March 2018; accepted 25 March 2018; online published-ahead-of-print 4 April 2018

Heart failure with reduced ejection fraction (HFrEF) is a systolic dysfunction with an ejection fraction below 40% and the prevalence of it is substantially increasing in the United States. Mechanical circulatory support (MCS) devices have increasingly been used for the management of HFrEF and are associated with improved outcomes. The National Inpatient Sample database was used to identify hospitalisations with mechanical circulatory support for HFrEF from 2005 to 2014. This study observed a reduction in the utilisation of intra-aortic balloon pump (IABP), which is partially replaced by percutaneous left ventricular assist device (pLVAD) and extracorporeal membrane oxygenation (ECMO) for the management of HFrEF. In-hospital mortality in IABP and ECMO recipients decreased during the study period while mortality with pLVAD did not change. Finally, technology for the short-term MCS in HFrEF hospitalisations continues to improve, however, there is still some space for updated technology in future.

Keywords Extracorporeal membrane oxygenation • Heart failure with reduced ejection fraction • Intra-aortic balloon pump • Mechanical circulatory support • Percutaneous left ventricular assist device

Heart failure hospitalisation is one of the most prominent reasons for hospital admissions in the United States and is substantially increasing [1]. Heart failure with reduced ejection fraction (HFrEF), a systolic dysfunction on echocardiography with reduced left ventricular function (ejection fraction ≤40%), is associated with substantial mortality and morbidity [2]. The frequency of HFrEF is thought to be as much as heart failure with preserved ejection fraction (HFpEF) [1]. Advancements in technology have paved the way for better outcomes associated with HFrEF and HFpEF. The use of various short-term mechanical circulatory support (MCS) devices has been increasing for the management of heart failure [3]; however, to our knowledge, no study is available demonstrating the utilisation of, and outcomes with, MCS in HFrEF hospitalisations. Therefore, the goal of this study was to analyse temporal trends in the utilisation and in-hospital mortality associated with MCS for the management of HFrEF.

The data for this study was obtained from the National Inpatient Sample database from 2005 to 2014 [4]. The details

Abbreviations: ECMO, extra corporeal membrane oxygenation; HFrEF, heart failure with reduced ejection fraction; IABP, intra-aortic balloon pump; MCS, mechanical circulatory support; pLVAD, percutaneous left ventricular assist device

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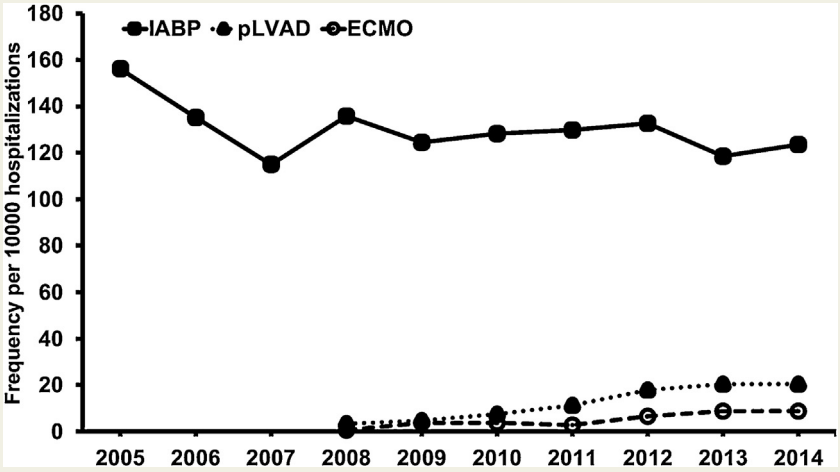

Figure 1 Utilisation of MCS devices per 10 000 HFrEF hospitalisations in the United States.
Utilisation of pLVAD and ECMO gradually increased, while utilisation of IABP decreased during the study period ($P_{trend} < 0.001$).
Abbreviations: MCS, mechanical circulatory support; HFrEF, HF with reduced ejection fraction; pLVAD, percutaneous left ventricular assist device; ECMO, extra corporeal ejection fraction; IABP, intra aortic balloon pump.

regarding this database have been published previously [3]. Briefly, this database represents nearly 95% of the hospitalisations of the United States and is publicly available. Adult (age ≥ 18 years) heart failure hospitalisations between 2005 and 2014 were identified using appropriate International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnosis codes in primary and secondary diagnosis fields. Hospitalisations with HFrEF were identified using 428.21 and 428.23 specific for acute systolic heart failures. To avoid systemic bias from this selection, all hospitalisations with combined systolic and diastolic heart failure hospitalisations were excluded. This method has been validated previously [1]. The utilisation of intra-aortic balloon pump (IABP) was identified using ICD-9-CM procedure code 37.61, percutaneous left ventricular assist device (pLVAD) using ICD-9-CM procedure code 37.68 and extracorporeal membrane oxygenation (ECMO) using ICD-9-CM procedure code 39.65 [3]. pLVAD includes Impella (Abiomed Inc., Danvers, MA, USA) TandemHeart (CardiacAssist, Inc., Pittsburgh, PA, USA) and TandemHeart devices. pLVAD and ECMO hospitalisations were not available prior to 2008. To generate national estimates, discharge trends provided by the Agency for Healthcare Research and Quality (AHRQ) were utilised. The analysis was conducted using SAS (SAS institute, Cary, NC, USA) 9.4 and in accordance with the required practices suggested by the AHRQ. Jonckheere-Terpstra Trend test was performed to analyse temporal trends during the study period. Mood's test was executed to compare median costs between the groups. A T-test was done to calculate differences in the length of stay; a p-value below 0.05 was considered significant.

Overall, 3,225,528 hospitalisations were identified with HFrEF from 2005 to 2014. The hospitalisations for HFrEF increased during the study period (27,879 in 2005 to 559,050 in 2014, $P\text{-}_{trend} < 0.001$). The use of MCS was performed in 1.40% of the hospitalisations: 1.27% IABP, 0.13% pLVAD and 0.05% ECMO. Trends of IABP use decreased eventually from 156 in 2005 to 123 in 2014 per 10,000 hospitalisations, while the six-fold increase in pLVAD use (3 in 2008 vs 20 in 2014 per 10,000 hospitalisations) and 15-fold increase in ECMO use (0.6 in 2008 vs 8.8 in 2014 per 10,000 hospitalisations) ($P\text{-}_{trend} < 0.001$ for all) (Figure 1). In-hospital mortality in IABP and ECMO recipients decreased from 21.5% in 2005 to 17.7% in 2014 and 75.1% in 2008 vs 44.9% in 2014 ($P_{trend} < 0.001$), respectively, while in pLVAD recipients, it remained unchanged over time (25.6% in 2008 vs 25.33% in 2014, P_{trend} 0.11) (Figure 2). The overall median cost associated with IABP hospitalisation was lower compared to pLVAD hospitalisations ($48,029 vs. $61,170, $p < 0.001$). Additionally, the median cost associated with ECMO hospitalisation was three-fold higher as compared to IABP hospitalisation ($48,029 vs. $149,040, $p < 0.001$). The median length of the hospitalisation stay was less when pLVAD were used (11 vs. 13 days, $p < 0.001$), compared to IABP. However, the median length of the hospitalisation stay was longer with ECMO as compared to IABP (16 vs. 13 days, $p < 0.001$). Additionally, more hospitalisations were sent home when using pLVAD as compared to IABP (39.2% vs. 33.8%, $p < 0.001$), while no difference in discharged to home with ECMO and IABP (33% vs. 33.8%, $p = 0.63$) were noted.

This study demonstrated a reduction in the utilisation of IABP, which was partially replaced by an increase in the utilisation of pLVAD and ECMO for the management of HFrEF. In-hospital mortality associated with IABP and ECMO reduced during the study period. Overall in-hospital mortality and median cost were higher when using pLVAD and ECMO. However, pLVAD use is associated with less resource utilisation and less length of stay.

As per the 2016 ESC guidelines for the diagnosis and treatment of acute and chronic heart failure [6], MCS can

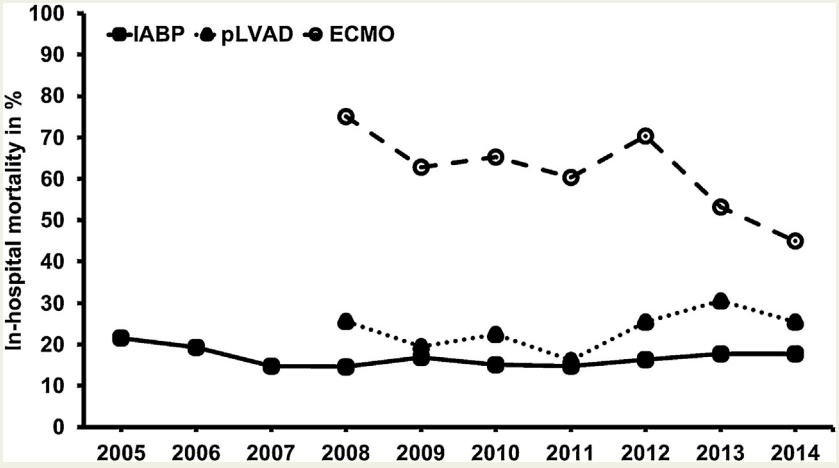

Figure 2 In-hospital mortality associated with MCS device in HFrEF.
In-hospital mortality in IABP and ECMO recipients decreased overtime during the study period ($P_{trend} < 0.001$).
Abbreviations: IABP, intra-aortic balloon pump, MCS, mechanical circulatory support; HFrEF.

be utilised to achieve different aims. They classify these as Bridge to Decision (BTD), Bridge to Bridge (BTB), Bridge to Candidacy (BTC), Bridge to Transplant (BTT), Bridge to Recovery (BTR) and Destination Therapy (DT). Guidelines around the use of IABP are currently restricted to their role in BTD and BTB. pLVAD can be utilised in this role but can also be used in BTC, BTT, BTR and DT. As a result, the comparison of mortality outcomes in patients receiving IABP and those receiving pLVAD is confounded by the fact that they are likely very different populations, receiving therapy for different indications.

Before the introduction of pLVADs into clinical practice, there was a lack of temporary MCS devices, which were mostly limited to IABP. Several factors have likely contributed to the national trends in utilisation of IABP, pLVAD and ECMO observed in this study. Firstly, compared with IABP, pLVADs provide more robust haemodynamic support as secondary outcomes within PROTECT II (A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk percutaneous coronary intervention) trial demonstrated better haemodynamic support compared to IABP [5]. Secondly, the percutaneous device delivery has minimised procedural invasiveness and enhanced ease of delivery with minimal complications. It also has expanded availability because devices can be implanted in the catheterisation laboratory without the need for surgical consultation. Finally, ESC guidelines have changed from only recommending left ventricular assist device (LVAD) use in the BTT population in 2005 to recommending its use in both the BTT and the DT/BTR groups in 2016. Conversely, ESC guidelines have weakened significantly with regards to IABP use in acute heart failure from a Class I Level B recommendation in 2003 [6]. However, this study demonstrated that pLVAD and ECMO implantation was associated with higher in-hospital mortality compared with IABP use. It is still possible that pLVAD and ECMO recipients in this study were sicker compared with IABP recipients because of unmeasured confounders (e.g., the severity of underlying illness, comorbidities, or high-risk coronary anatomy). Nonetheless, pLVADs are promising devices since they provide active circulatory support, while IABP requires a certain residual level of left ventricular function. The median cost of hospital stay in pLVAD and ECMO recipients was higher than IABP, which can be associated with higher device cost itself. Longer length of stay with ECMO may contribute to its three-fold higher hospitalisations cost to IABP. Finally, pLVAD is associated with less resource utilisation as seen by lower length of stay and more discharges to home may suggest a potential benefit of using it for carefully selected patients.

Inherent limitations associated with any retrospective study apply to this study. Increasing admission for HFrEF in this study may be associated with the evolution of the definition of HFrEF during the study period. Additionally, a systematic and longitudinal collection of data pertaining to IABP and pLVAD therapy for HFrEF is warranted to ensure improved outcomes in the future. Although ECMO use was associated with higher in-hospital mortality compared to IABP and pLVAD, one needs to understand that the indications are different for these devices.

In conclusion, the technology of short-term MCS is still in the process of evolution. Newer mechanical circulatory support devices such as pLVADs may demonstrate improved outcomes in the acute setting of heart failure. In future, comparisons of the use of different forms of MCS would need to consider the role of ECMO in the acute setting of HFrEF. More studies with meticulous follow-ups are needed to formulate guidelines and appropriate use criteria for identifying the best patient and the best time for using MCS.

Acknowledgement

None.

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