Int J Heart Fail. 2024 Apr;6(2):82-83
https://doi.org/10.36628/ijhf.2024.0023
pISSN 2636-154X·eISSN 2636-1558

International Journal of Heart Failure IJHF

Editorial

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Another, A Few Good Device for End Stage Heart Failure

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▸ See the article "Adverse Events in Total Artificial Heart for End-Stage Heart Failure: Insight From the Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE)" in volume 6 on page 76.

Received: Apr 15, 2024
Accepted: Apr 18, 2024
Published online: Apr 23, 2024

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The gold standard for treating end-stage heart failure treatment is heart transplantation. However, the tremendous scarcity of the donor hearts often leads to patients died on the waitlist before a transplant.[1] To address this issue, mechanical circulatory support devices, such as left ventricle assisted device (LVAD) and total artificial heart (TAH), have emerged as alternatives to compensate the failing heart.[2] Currently, TAH is not available in Korea, but in the United States, TAH is considered for patients with biventricular failure or with other structural conditions that make them incompatible with receiving LVAD.[1] The SynCardia TAH (SynCardia Systems, Tucson, AZ, USA) is the most frequently implanted TAH and serves as a bridge to transplant (BTT), not as a destination therapy.[2] Furthermore, the survival rate of patients who undergo transplantation after TAH is comparable to that of the de novo transplant patients or those who receive LVAD as BTT, provided they survived early post-operative period at one year.[3] Despite of these promising outcomes, the bulky in size and increase in device-related complication rates are significant limitations that hinder the widespread implantation of current TAH devices.[1] Furthermore, close monitoring should be advised in the post-implant phase, especially when employed as BTT.

In this issue of the journal, Tan et al.[4] present findings on adverse events associated with the use of SynCardia TAH reported to Food and Drug Administration's Manufacturers and User Defined Experience (MAUDE) database from 2012 to 2020. A total of 1,512 adverse events were identified in 453 cases, with infection (20.2%) being the most prevalent followed by device malfunction (20.1%) after TAH implantation. All cause death was reported in 49.4% (n=224) of the cases, primarily attributed to multiorgan failure (n=73, 32.6%).

While the findings of this paper provide an outline of adverse events to be aware of in clinical practice, it is important to consider some limitations before interpreting the results and generalizing the conclusions to the real world. First of all, due to the lack of overall TAH implantation data across the United States, it is impossible to determine the event rates or the incidence of the device-related complications. As a result, the adverse events of the device were acknowledged, yet the casualty between the increase in event occurrence with increased in either the number of implantation or device related malfunction is questionable. Secondly, the absence of hospital-specific data is crucial while only reported events are available in MAUDE database. Consequently, it is unclear whether the outcomes are better in high-volume centers or if certain hospitals have higher incidence of adverse events compared to others. Also, due to the reporting bias, voluntary and not mandated, which is the major logistic impediment of the MAUDE

database, the severity of the reported adverse events is skewed. Furthermore, with the absence of the data upon patients' comorbidities and time interval from the implantation, the independent predictors and time-event casualty of adverse event remains in obscure. Even so, although this paper has few inherent limitations, it calls forth the importance of the prompt recognition and adept handling of any adverse events to augment the outcomes of TAH.[5]

Currently, with recent attempts have been made to explore xenotransplantation in patients who are compelled to undergo TAH due to limited alternatives, further studies are warranted for adjunct treatments in end-stage heart failure.

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Conflict of Interest
The authors have no financial conflicts of interest.

Author Contributions
Conceptualization: Lee J, Oh J; Supervision: Kang SM, Oh J; Writing - original draft: Lee J, Oh J; Writing - review & editing: Oh J.

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