Commentary: The search for left ventricular assist device outflow tract obstruction

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“You can know anything. It’s all there. You just have to find it.”

—Neil Gaiman

Wert and coauthors present a timely and insightful analysis of a cryptic problem in left ventricular device support with the HeartMate 3—outflow graft obstruction (OGO)—in “A Multicenter Evaluation of External Outflow Graft Obstruction With a Fully Magnetically Levitated Left Ventricular Assist Device” in this issue of the Journal. In this analysis, the authors have assembled a cohort of more than 2100 patients in 17 centers in 8 countries in Asia, Europe, and North America. In this study, the authors analyze institution- and patient-level data to determine the incidence and prevalence of this problem and provide guidance to the community on clinical detection and program management. This report is exactly the kind of collaboration and scholarship-driving clinical guidance that Wert and colleagues have provided time and time again.

The strengths of this study include its diverse inclusion and large cohort, which drive the presented data to provide insights into the natural history, detection, and results of therapeutic intervention. The occurrence of outflow graft obstruction is particularly vexing, as the exact incidence and prevalence alone have been hard to define. The contribution of patient, device, and surgical factors has been speculative in this device while it emerged from clinical trials into clinical practice. Although all surgeons see gelatinous material in the same area of obstruction to some degree in all left ventricular assist devices at explant/transplant, the mystery lies in why some go on to obstruction and others reach benign equilibrium.

This study importantly helps define the natural history and drives several important conclusions:

1. The occurrence of this complication is uncommon. This study reports the prevalence at 3% with an escalating incidence at 1, 2, 3, 4, and 5 years on support of 0.6%, 2.8%, 4.0%, 5.2%, and 9.1%.
2. OGO as defined has historically been detected at a high degree of stenosis/obstruction.
3. The morbidity and mortality of OGO treatment are significant. As reported, surgical and/or percutaneous stenting was associated with high mortality, whereas urgent transplantation was successful.
4. The impact of early detection is undefined, as are the best current treatment and best screening protocol in the current era.

This study’s data and conclusions are important; however, important limitations to the current study remain. The representative nature of this ad hoc but large geographically diverse group is not known. Although the cohort is large, it may not be representative of all patients in all areas. Leadtime bias and competing events of transplantation make knowing the exact prevalence and incidence difficult, as...
well as the impact of preventative interventions. The prevalence/incidence proposed in the study is probably representative enough to guide decisions for clinical management and drive screening efforts. The variable incidence and availability of transplants in different centers makes the true incidence of this problem and its time-dependent risk difficult to calculate.

Regrettably, the study does not take advantage of its multicenter patient-level data to dissect the problem completely. A lack of granular data on all patients is the greatest limitation of this study—data on surgical technique, pathology, and complication-free support duration are critical to truly understanding the nature and risk of this complication. Further, for simplicity, the authors separated the issue of outflow graft twisting from their OGO analysis. This decision makes sense from the analysis and engineering standpoints, as there is an engineering fix for that occurrence. However, the possibility of inherently increased graft motion may contribute to fluid accumulation and subsequent obstruction may be related.

Despite the large study size, the number of patients detected with OGO remains small, as are the number and grouping of interventions, making comparisons difficult. For example, as noted, the authors show that percutaneous intervention in the small groups has not been as successful as other interventions in previous outflow problems in other devices, for unclear reasons.

Where the authors impart significant causation to the device design and surgical technique during implantation, the precise causation remains unknown. The distribution of OGO in the center data, as well as an absence of a detected center effect (as a surrogate for surgeon effect) is telling. Is this complication surgeon-driven, device-driven, or patient-dependent? Even this large cohort cannot truly elucidate the cause. Lastly, of course, the time to develop this complication is the most vexing component to understanding. Small decisions in the operating room may lead to this complication years later. Certainly, the authors’ lack of data regarding surgical technique and deviations from the manufacturer’s recommended techniques and instructions is limiting. Do deviation and innovation prevent or contribute to its occurrence? We still lack these important data to inform our clinical management. In the end, the data presented in the current report reinforce that the causation of outflow tract obstruction is likely multifactorial.

Despite the utility and insight that Wert and coauthors’ analysis provides, we are left with important questions regarding the best screening protocols, best surgical technique to mitigate this complication, and, of course, the best treatment when detected.

References