Continuous-flow ventricular assist device exchange is safe and effective in prolonging support time in patients with end-stage heart failure

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Objective: Although the development of continuous-flow ventricular assist devices (CF-VAD) has improved the reliability of these devices, VAD exchange is still occasionally necessary. The focus of this study was to analyze our institution's entire experience with primary CF-VAD implants, evaluate the baseline variables, determine which factors predict the need for exchange, and evaluate the impact of exchange on survival and event-free survival.

Methods: We retrospectively reviewed the data of all patients in a single center who received a primary CF-VAD implant between December 1999 and December 2013. All CF-VAD exchanges were reviewed; demographics, indications, preoperative and operative data, and clinical outcomes were summarized. Univariate and multivariable regression analyses were performed to ascertain predictors for exchange. Time-to-event and survival analyses were also performed.

Results: We identified 469 patients who underwent 546 CF-VAD implantations. Of these patients, 66 (14%) underwent 77 exchanges from one CF-VAD to another. The primary indications included hemolysis or thrombosis (n = 49; 63.6%), infection (n = 9; 11.7%), or other causes (n = 19; 24.7%). Survival was not significantly different between the exchange and nonexchange groups. Multivariable regression analysis identified a history of cerebrovascular events as a significant predictor for exchange. Among exchange patients, 11 underwent heart transplantation, 3 had their CF-VADs explanted, 26 had ongoing support, and 26 died during device support.

Conclusions: In our series of contemporary CF-VAD exchanges, a history of previous cerebrovascular events was a significant predictor for exchange. Exchange did not affect early or late survival. Our data suggest that aggressive surgical treatment of pump-related complications with exchange is safe and justified. (J Thorac Cardiovasc Surg 2015;149:267-78)

See related commentary on pages 279-80.

Supplemental material is available online.

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The use of continuous-flow ventricular assist devices (CF-VADs) has had a major impact on our ability to successfully treat end-stage cardiac disease. CF-VADs can be used as a bridge to transplantation, a bridge to recovery, or as destination therapy with meaningful clinical results.[1-8]

Over the past decade, mechanical circulatory support (MCS) devices have supported thousands of patients with excellent overall outcomes,[5] particularly compared with medical therapy alone.[9] The experience with this technology continues to rapidly expand; more than 12,000 patients have been enrolled in the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) since 2006 in the United States alone.

In comparison with first-generation devices, CF-VADs perform with remarkably improved durability and overall clinical outcomes.[10,11] However, adverse events, such as hemolysis, bleeding, thrombosis, infection, stroke, and mechanical failure, continue to be important and potentially devastating problems associated with this therapy.[5,12-15] When the adverse event is associated with a pump-related

Abbreviations and Acronyms

CI	= confidence interval
CF-VAD	= continuous-flow ventricular assist device
CPB	= cardiopulmonary bypass
INTERMACS	= Interagency Registry for Mechanically Assisted Circulatory Support
MCS	= nechanical circulatory support
OR	= odds ratio
SD	= standard deviation
VAD	= ventricular assist device

problem, it can often be managed by expeditious device exchange. Several groups, including our own, have demonstrated that judicious device exchange can potentially overcome some of the catastrophic consequences of such ventricular assist device (VAD)-related adverse events.[16-24] The focus of this study was to analyze our institution's entire large experience with primary CF-VAD implants; to evaluate the baseline variables; and to determine which factors predict the need for exchange and the impact of exchange on survival and event-free survival.

METHODS

Study Cohort

Institutional Review Board approval with appropriate informed consent was obtained to perform a retrospective review of our center's patient database. All patients implanted with any CF-VAD between December 1999 and December 2013 were identified. Within this population, we identified those patients who underwent 1 or more VAD exchanges. Our aim was to compare the cohort of patients with VAD exchange with the cohort without exchange within the overall population of contemporary CF-VAD recipients. Any patient who had received a durable, non–CF-VAD at any point during their clinical course was excluded from this analysis.

Primary End Points

Demographics, indications, echocardiographic and hemodynamic parameters, operative, perioperative, and late clinical outcomes data were reviewed and summarized. Our primary aim was to determine significant independent predictors for VAD exchange. Secondary end points were overall survival and event-free survival while on VAD support and to the date of last follow-up. Event-free survival was defined as freedom from death, transplant, or VAD explant. The significance of VAD exchange as an independent predictor of survival was also evaluated.

Statistical Analysis

Demographics, indications for support, operative data, and clinical outcomes were compared between the CF-VAD exchange and nonexchange cohorts. Continuous variables were analyzed with the 2-sample t test, and categorical variables with the χ^2 or Fisher exact test. Means are presented with standard deviations.

Our primary aim of ascertaining predictors of VAD exchange was achieved using multivariable logistic regression modeling. We included all univariate variables that differed between the 2 cohorts ($P < .05$, or $P < .1$ trend), as well as all clinically relevant variables of interest. We did not include multiple correlated variables. Stepwise regression was performed eliminating all variables with $P > .1$. The result was a parsimonious clinically relevant model. This was performed for VAD exchange as the outcome variable, and repeated for overall survival and survival while on VAD support as the outcome, with VAD exchange remaining in the predictor model.

Time-to-event survival analysis was performed creating Kaplan-Meier curves. Both the log-rank and the Wilcoxon tests were used to compare differences between the cohorts.

Late follow-up was complete for 95% of patients for a mean time period of 2.1 ± 2.4 years (maximum, 13.3 years). There was minimal missing data (<5%) for all variables and/or data points. For all analyses, P values were 2-sided. Analyses were conducted with the R statistical software (Vienna, Austria).

RESULTS

Patient Characteristics

During our study period (December 1999 to December 2013), 469 patients underwent 546 CF-VAD implantations. Initially implanted pumps included the HeartMate II (Thoratec, Inc Pleasanton, Calif; n = 327), the Jarvik 2000 (Jarvik Heart Inc, New York, NY; n = 74), the HeartWare HVAD (HeartWare, Inc, Miami Lakes, Fla; n = 65), the DuraHeart (Terumo Heart, Inc, Ann Arbor, Mich; n = 2), and the MicroMed DeBakey (MicroMed Inc, Houston, Tex; n = 1). Of these patients, 66 underwent 77 VAD exchanges from their existing device to another CF-VAD; a 14% exchange incidence. The exchanged devices included the HeartMate II (n = 59), the Jarvik 2000 (n = 10), and the HeartWare HVAD (n = 8) devices. These devices were exchanged for the HeartMate II (n = 52), the Jarvik 2000 (n = 10), and the HeartWare HVAD (n = 15) devices. Total exchange rates for each device were 0.13 events per patient-year (15.5%) for the HeartMate II, 0.29 events per patient-year (11.9%) for the Jarvik 2000, and 0.16 events per patient-year (10%) for the HeartWare HVAD.

Table 1 lists the baseline device, demographic, clinical, echocardiographic, and invasive hemodynamic data, and the operative and postoperative outcomes of the CF-VAD exchange cohort (n = 66 patients) and compares them with the corresponding data from the nonexchange cohort (n = 403 patients). There was a similar proportion of bridge to transplantation versus destination therapy indications in both groups. The group with 1 or more VAD exchanges had statistically longer duration of VAD support, more preoperative cerebrovascular events, higher platelet count and albumin levels, less INTERMACS class 1 status, and less frequently used preoperative temporary MCS (eg, Impella, Tandem Heart, intra-aortic balloon pump, and/or extracorporeal membrane oxygenation [ECMO]).

Exchange Cohort

Table 2 summarizes the characteristics of the 66 patients who underwent 1 or more VAD exchanges and the rates of exchange by device. Hemolysis/suspected thrombosis was the primary indication (64%). Surgical