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Heart transplantation outcomes in patients with continuous-flow left ventricular assist device-related complications

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BACKGROUND: Device-related complications (DRC) can develop in patients supported with continuous-flow left ventricular assist devices (CF-LVADs). We studied the heart transplant (HTx) outcomes of United Network of Organ Sharing (UNOS) Status 1A patients supported with CF-LVADs with (+) or without (–) DRCs.

METHODS: UNOS data (2006 to 2012) for patients listed under Status 1A with CF-LVADs at the time of HTx were analyzed. Outcomes were compared between the DRC+ and DRC– groups. The DRC+ group was further analyzed under 5 UNOS categories: B1 to B5.

RESULTS: Of the 6,799 patients who received HTx under 1A listing, 2,113 (31%) were supported with CF-LVADs. From 2006 to 2012, patients supported with CF-LVADs under the 1A listing increased from 11.4% to 41.5% ($p = 0.0001$). The DRC+ group (45%) compared with the DRC– group (55%) had longer waiting times (330 ± 323 days vs 168 ± 298 days), more patients with blood group O (57% vs 40%), and a higher body mass index (29 ± 5.5 kg/m^2 vs 27 ± 5 kg/m^2). Most of the DRCs were in the B2 category (54%). Post-HTx survival for the DRC+ group was significantly reduced compared with the DRC– group at 1 year (85.6% vs 89.9%, $p = 0.01$) and at 3 years (78% vs 82.7%, $p = 0.01$), primarily due to B2 category.

CONCLUSIONS: An increasing number of patients receiving HTx under 1A listing are supported with CF-LVADs. DRCs are steadily increasing, with most of them from the B2 category. Post-HTx survival in DRC+ group is inferior, primarily for the B2 category. The benefits of CF-LVADs for patients awaiting HTx need to be weighed against the development of DRCs with subsequently inferior post-HTx survival.

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As waiting times for heart transplantation (HTx) have increased, more patients are supported with left ventricular assist devices (LVADs) as a bridge to transplantation.[1,2] In addition, newer-generation LVADs are better designed and are more durable than before.[3] Blood flow in these newer generation of devices is continuous (CF) rather than pulsatile. In clinical trials, CF-LVADs fared better compared with the previous generation of LVADs and are now the preferred choice of circulatory support for patients with end-stage heart failure.[4,5] Taken together, increasing waiting times for HTx and better survivability associated with newer LVADs are extending the duration that patients remain supported by these devices.

The longer duration of support on an LVAD may expose patients to attended device-related complications (DRCs) that increase the severity of illness at the time of HTx. Although the post-HTx outcomes of patients supported with

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Table 1 Continuous-Flow Left Ventricular Assist Device-Related Complication Sub-groups

Group	Complication
B1	Thromboembolism
B2	Device-related infection
B3	Device malfunction
B4	Recurrent ventricular arrhythmias
B5	Other complications

CF-LVADs are comparable overall with those who received HTx without device support,[6] it is possible that outcomes would be influenced negatively by the higher acuity of illness in HTx recipients with DRCs. A previous study found no differences in the clinical outcomes of patients who had DRCs at the time of HTx compared with those without DRCs.[7] However, most of the patients in that study were supported with pulsatile-flow devices that are not currently used, had shorter waiting times for HTx, and had fewer DRCs, making the study findings less valid for today's CF-LVAD patients.

According to United Network of Organ Sharing (UNOS) guidelines, patients supported with LVADs are eligible for Status 1B listing for HTx. However, they may also be listed as Status 1A candidates by using the assigned 30-day post-LVAD implantation time or if a DRC develops. UNOS defines DRCs by dividing the events into 5 sub-groups according to the type of LVAD-related complication (Table 1). Because most patients with DRCs are up-listed to 1A status, we chose to study the influence of each of the 5 UNOS sub-groups of DRCs on HTx outcomes among all CF-LVAD–supported patients with Status 1A listing.

Methods

UNOS, in collaboration with the Organ Procurement and Transplantation Network, maintains a national database on all patients listed for organ transplantation and tracks their clinical outcomes after transplantation.[1]

We analyzed the UNOS data of patients aged older than 18 years who received HTx as Status 1A candidates between January 2006 and December 2012. From this patient pool we selected only those who were supported with CF-LVADs at the time of HTx and grouped them by those with (+) and without (–) DRCs. A detailed analysis of data was performed using the SAS 9.3 software (SAS Institute Inc, Cary, NC). Categoric variables were analyzed using the chi-square test or the Fisher's exact test and are reported as percentages. Continuous variables were analyzed with the Student's *t*-test or the Wilcoxon rank sum test and are reported as mean, median, and standard deviations. *P* values of <0.05 are considered statistically significant. In addition, post-HTx outcomes of the 5 sub-groups of DRC+ patients were individually compared with the DRC– group.

Results

During the study period, 6,799 patients received HTx under Status 1A listing; of whom 2,113 (31%) were supported with CF-LVADs at the time of HTx. Overall, there was a steady upward trend in the number of patients supported with CF-LVADs who received HTx as 1A candidates, rising from 11.4% in 2006 to 41.5% in 2012 (Fig 1). Among the patients supported with CF-LVADs at the time of HTx, DRCs occurred in 45.1%; of these, 54% (513 patients) of the DRCs were in the B2 category, followed by B3 in 18.4% (175 patients), B1 in 17.4% (166 patients), B5 in 17.4% (166 patients), and B4 in 6.6% (63 patients) (Table 2). During the study period, the prevalence of Status 1A patients supported with CF-LVADs whose listing status was attributable to DRCs increased from 20% in 2006 to 55% in 2012 ($p = 0.0001$). Although all DRCs (B1–B5) increased over time, most of the increase was noted in the B2 category (Figure 2).

The characteristics of DRC+ patients compared with the DRC– patients are summarized in Table 3. The mean age of patients was similar between the two groups, at 52 years,

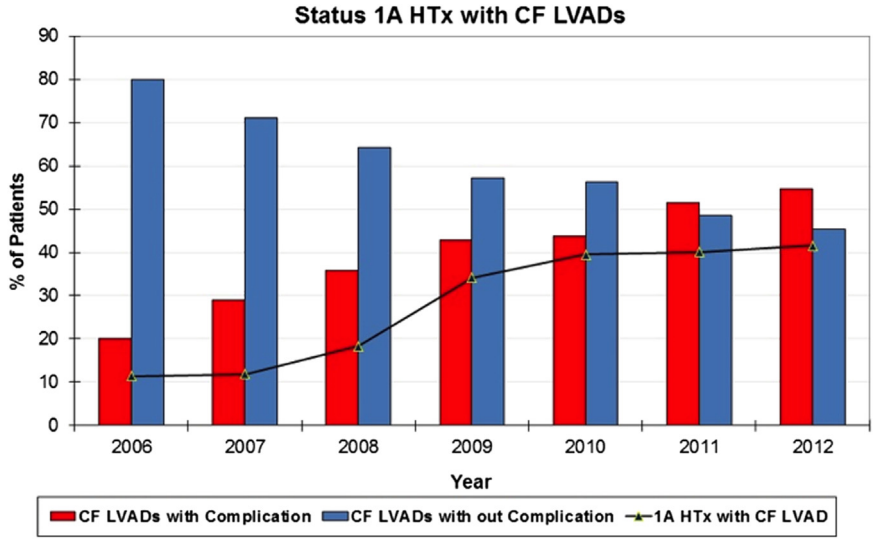

Figure 1 Device-related complications in patients supported with a continuous-flow left ventricular assist devices (CF LVADs) who received heart transplantation (HTx) as 1A candidates.