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ORIGINAL ARTICLE

Cardiac Transplantation After Bridged Therapy with Continuous Flow Left Ventricular Assist Devices

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Introduction Cardiac transplantation is an effective surgical therapy for end-stage heart failure. Patients (pts) may need to be bridged with a continuous flow left ventricular assist device (CF-LVAD) while on the transplant list as logistic factors like organ availability are unknown. Cardiac transplantation post-LVAD can be a surgically challenging procedure and outcome in these pts is perceived to be poorer based on experience with earlier generation pulsatile flow pumps. Data from a single institution comparing these pts with those undergoing direct transplantation in the present era of continuous flow device therapy are limited.

Aim Evaluate results of cardiac transplantation in pts bridged with a CF-LVAD (BTx) and compare outcomes with pts undergoing direct transplantation (Tx) in a single institution.

Results From June 2007 till January 2012, 106 pts underwent cardiac transplantation. Among these, 37 (35%) pts (51 ± 11 years; 85% male) were bridged with a CF-LVAD (BTx), while 70 (65%) comprised the Tx group (53 ± 12 years; 72% males). The median duration of LVAD support was 227 (153,327) days. During the period of LVAD support, 10/37 (27%) pts were upgraded to status 1A and all were successfully transplanted. Median hospital stay in the BTx (14 days) was slightly longer than the Tx group (12 days) but not statistically significant ($p = 0.21$). In-hospital mortality in the BTx (5%) and Tx (1%) were comparable ($p = 0.25$). Estimated late survival in the BTx cohort was 94 ± 7, 90 ± 10 and 83 ± 16% at the end of one, two and three years, respectively which was comparable to 97 ± 4%, 93 ± 6% and 89 ± 9% for the Tx group ($p = 0.50$).

Conclusion Cardiac transplantation after LVAD implant can be performed with excellent results. Patients can be supported on the left ventricular assist device even for periods close to a year with good outcome after cardiac transplantation.

Keywords Cardiomyopathy • Circulatory assist devices • Transplantation (heart) • Heart failure • Surgical therapy

Introduction

The proportion of patients with end-stage congestive heart failure is increasing exponentially. Even after listing the candidate as status IA, organ availability, patient's blood group and many such factors dictate the wait times for an eventual transplant. Bridging patients with a ventricular assist device is now an accepted therapy for patients on the transplant waiting list. The current generation of continuous flow devices (CF-LVAD) needs reduced surgical

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dissection for implantation, reduced post-operative blood loss and less complications in the post-operative support period.

We present our results with cardiac transplantation in the era of CF-LVAD bridge therapy and retrospectively compare outcomes between patients who underwent direct cardiac transplantation (Tx) and those bridged with a CF-LVAD (BTx) at our institution.

Patient and methods

After Institutional Board Review approval, a retrospective data analysis was conducted of 106 consecutive adult patients who underwent cardiac transplantation at our institution from June 2007 till January 2011. The UNOS® (United Network for Organ Sharing) activation date, duration of wait time till transplant, initial UNOS® status and subsequent changes were obtained and analysed for all patients. Data regarding pre-transplant clinical condition, laboratory variables and haemodynamic parameters were collected and analysed for all patients. For the Btx cohort, surgical details of LVAD implant, duration of LVAD support, and the presence of any complications during the support period were collected from our prospectively maintained LVAD registry. Early adverse outcomes including post-operative bleeding needing re-exploration, respiratory failure, renal failure and neurological events were compared between Tx and BTx pts. Follow-up was obtained from regular post-operative clinic visits, and correspondence received from treating physicians at other centres.

The CMS criteria for device therapy were implemented to make the decision to bridge pts with an LVAD. All pts underwent LVAD implant at our institution via a median sternotomy in the routine manner. Rigorous follow-up was conducted by our LVAD coordinators to ensure adherence of appropriate anticoagulation and driveline site care protocols. Re-admissions for LVAD related complications were done at our institution or communicated to us from the admitting centre. Pre-transplant evaluation was conducted at regular intervals for all pts on the wait list.

Orthotropic heart transplantation was performed via median sternotomy under moderate hypothermia for all pts. A bi-caval or a bi-atrial anastomotic technique was performed as per patient factors and surgeon's discretion. Selection of donors was conducted as per institutional protocol. Marginal donors were not considered as candidates for organ donation. Our immunosuppressive therapy regime did not differ depending upon the presence/absence of an LVAD.

Statistical analysis

Statistical analysis has been conducted with JMP9.0® for Windows OS (SAS Inc., Cary, NC, USA). Nominal data have been presented as number (percentages). Continuous data have been appropriately presented as mean ± SD or median (interquartile range). Categorical variables are compared using the Fisher's exact test while continuous data are analysed with the *T*-test or the Wilcoxon test as per normality. The two-tailed p-value <0.05 is considered significant for all statistical analyses and 95% confidence intervals are mentioned where appropriate.

Kaplan–Meier curves have been generated to estimate survival. The log-rank method has been used to compare the Tx and BTx cohorts.

Results

During the study period, 106 pts (mean age 52.8 ± 11.5 years, male 76%) underwent orthotropic cardiac transplantation. The detailed pre-operative variables in both groups are outlined in Table 1. 37/106 (35%) pts were bridged with a left ventricular assist device (Btx) while the remaining 69/106 (65%) underwent transplant directly (Tx). More patients in the Btx category were initially listed as UNOS IA (22% vs 6%; $p = 0.02$). Patients with blood group O experienced the longest median wait-time (303 days) while in the AB group pts received a heart with the shortest wait time (31 days). A larger proportion of pts (83%) who underwent LVAD bridging were from either blood group O or A ($p = 0.08$).

In the entire cohort, 6/106 (14%) pts had a PRA > 10% pre-transplant; in these six pts, two (3%) were from the Tx cohort and the remaining (11%) from the BTx group ($p = 0.18$).

BTx cohort

During the study period, 37 pts (mean age 50.9 ± 11 years; male 86%) who were bridged with a CF-LVAD underwent transplantation. The HeartMate II (Thoratec Corp., Pleasanton, CA) was present in 24 pts, while the rest underwent implantation with the Jarvik device (5), Ventrassist (6) or the DuraHeart LVAD (2). The median wait time from UNOS listing to transplant was 278 (147,537) days. These pts were supported on the LAVD for a median duration of 227 (153,328) days. Among these pts, 22% were listed as UNOS status IA before LVAD implantation. Among these 37 pts, 14 (37%) were upgraded to UNOS status IA due to issues with the left ventricular assist device. In eight pts, the reason was LVAD related intravascular haemolysis; in five it was mechanical problems and power surges, while one had persistent driveline infection. All pts with LVAD complications were upgraded to status IA and successfully underwent cardiac transplantation. Only one pt needed a pump exchange due to severe intravascular haemolysis while waiting for transplantation.

Our 30-day and one-year survival for LVAD implant as BTT during the same study period is 93% and 87 ± 10%, respectively.

Early post-operative period (X) (Table 2)

Operative duration for cardiac transplantation was longer for the Btx cohort (398 ± 103 min) as compared to the Tx group (316 ± 188 min) of pts ($p = 0.005$). PRBC (packed red blood cell) transfusion was more in the BTX cohort (median 7 units)