Durability of central aortic valve closure in patients with continuous flow left ventricular assist devices

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Background: A competent aortic valve is essential to providing effective left ventricular assist device support. We have adopted a practice of central aortic valve closure by placing a simple coaptation stitch at left ventricular assist device implantation in patients with significant aortic insufficiency. We conducted a follow-up study to evaluate the efficacy and durability of this procedure.

Methods: The study included patients who had undergone continuous flow left ventricular assist device implantation. The patients were divided into 2 groups, those who did not require any aortic procedure because the valve was competent and those who underwent central aortic valve closure for mild or greater aortic regurgitation. The clinical endpoints were mortality, progression or recurrence of aortic insufficiency, and reoperation for aortic valve pathologic features. Aortic insufficiency was measured qualitatively from mild to severe on a scale of 0 to 5.

Results: A total of 123 patients received continuous flow left ventricular assist devices from February 2007 to August 2011. Of those, 18 (15%) underwent central aortic valve closure at left ventricular assist device implantation because of significant aortic insufficiency (1.8 ± 1.4) and 105 who did not (competent aortic valve, 0.15 ± 0.43; $P < .01$). At follow-up (median, 312 days; range, 0-1429 days), the mean aortic insufficiency score remained low for the patients with central aortic valve closure (0.27 ± 0.46) in contrast to those without central aortic valve closure who experienced aortic insufficiency progression (0.78 ± 0.89; $P = .02$). In addition, the proportion of patients with more than mild aortic insufficiency was significantly less in the central aortic valve closure group (0% vs 18%; $P = .05$). The patients in the central aortic valve closure group were significantly older and had a greater incidence of renal failure at baseline. The 30-day mortality was greater in the central aortic valve closure group, but the late survival was similar between the 2 groups. No reoperations were required for recurrent aortic insufficiency.

Conclusions: The results of our study have shown that repair of aortic insufficiency with a simple central coaptation stitch is effective and durable in left ventricular assist device-supported patients, with follow-up extending into 2 years. Although aortic insufficiency progressed over time in those with minimal native valve regurgitation initially, no such progression was noted in those with central aortic valve closure. Additional investigation is needed to evaluate whether prophylactic central aortic valve closure should be performed at left ventricular assist device implantation to avoid problematic aortic regurgitation developing over time, in particular in patients undergoing left ventricular assist device implantation for life-long (destination therapy) support. (J Thorac Cardiovasc Surg 2014;147:344-8)

A competent aortic valve is essential for optimal hemodynamics in patients with left ventricular assist devices (LVADs) to allow forward, and not ineffective, circular, systemic blood flow.[1] Several methods are available for correcting native aortic insufficiency (AI), including aortic valve replacement,[2] patch closure of the aortic root,[3] complete aortic valve closure,[4] and central aortic valve closure (CAVC), consisting of partial closure of the aortic valve cusps, reported as Park's stitch.[5] CAVC has the potential to be the ideal technique, because it is inexpensive, quick, and simple to perform and might not have the same degenerative potential as biologic valve prostheses. Although the short-term durability of CAVC has been described in patients receiving pulsatile LVADs, its efficacy in nonpulsatile LVADs and its long-term durability are unknown. We, therefore, reviewed our experience of CAVC in patients receiving nonpulsatile LVADs to evaluate its efficacy and durability.

METHODS

The institutional review board approved our research involving human subjects. The need for written informed consent was waived owing to the minimal risk nature of the present study, but all patients had given consent

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Abbreviations and Acronyms
AI = aortic insufficiency
CAVC = central aortic valve closure
LVAD = left ventricular assist device

for research. The data were obtained from our prospectively collected electronic LVAD database and through our institution's electronic medical record, which includes all inpatient, outpatient, and imaging records. The study group consisted of patients who had undergone CAVC and the control group consisted of patients who had not. During the same period, 7 patients underwent aortic valve replacement for aortic valve repeat replacement of a mechanical valve prosthesis or suture closure of a mechanical valve prosthesis. Because our clinical question was the durability of the central coaptation stitch (not a comparison of various techniques), these 7 patients were excluded from the present analysis.

The primary endpoint of the present study was the durability of CAVC as assessed by echocardiography, as described previously.[6] The baseline assessment of AI was ascertained by preoperative surface and intraoperative transesophageal echocardiography. Postoperative echocardiography was performed monthly and as needed in our LVAD population, usually monthly. The degree of AI was qualitatively scored on a 5-point scale as follows: 0, none; 1, mild; 2, mild-to-moderate; 3, moderate; 4, moderate-to-severe; and 5, severe. This corresponds to the American Society of Echocardiography[7] standards of none (Mayo score, 0), mild (Mayo score, 1), moderate (Mayo score, 3), and severe (Mayo score, 5). We categorized the patients by the indication for LVAD support as receiving either bridge-to-transplant or destination therapy. The secondary end points consisted of early (within 30 days of LVAD implant) and late mortality and the need for reoperation for aortic regurgitation.

The technique of CAVC using a central coaptation stitch has been previously described for patients with central regurgitation of native AI.[5] In brief, after initiation of cardiopulmonary bypass, the aorta was crossclamped and diastolic arrest of the heart was initiated by either antegrade or retrograde cardioplegia. An oblique aortotomy was made at the site of the LVAD outflow graft anastomosis. The 3 aortic valve cusps were coapted centrally with one 5-0 polypropylene monofilament suture with small felt pledgets in each cusp (Figure 1). The aortic outflow graft was anastomosed in the usual fashion, and the aortic crossclamp was released.

Statistical analyses were performed using JMP, version 9.0.1 (SAS Institute, Cary, NC). Owing to the small sample size, nonparametric analyses were performed. The continuous variables are presented as the mean ± standard deviation and were compared using the Kruskal-Wallis test for heterogeneity. Categorical variables are reported as percentages and were statistically examined using Fisher's exact test, as appropriate.

RESULTS

A total of 123 patients received continuous flow LVADs during the study period. Of those, 18 (15%) underwent CAVC for AI. The mean age of all patients at LVAD implant was 60 years; however, those undergoing CAVC were older (66 ± 11 vs 59 ± 14 years; $P = .03$). The etiology of heart failure was ischemic in just fewer than one half the patients (47%) and did not differ between the 2 groups. The 2 groups did differ with respect to a greater incidence of pre-existing chronic renal insufficiency and more patients receiving LVAD therapy for destination therapy in the group undergoing CAVC. The complete patient demographic data are presented in Table 1.

The CAVC group had longer cardiopulmonary bypass times (155 ± 61 vs 108 ± 43; $P < .01$. Aortic crossclamping was more frequent in the CAVC group (100% CAVC vs 13% no CAVC; $P < .01$). For those patients in both groups who underwent aortic crossclamping (for all concomitant procedures), however, no difference was present in the aortic crossclamp time (42 vs 41 minutes, respectively; P = NS). Early survival favored those without CAVC (97% vs 78%; $P = .01$). However, for those who survived, no difference was found in the length of hospital stay (23 ± 16 vs 26 ± 21 days). The complete intraoperative and early postoperative data are presented in Table 2. The early deaths in the CAVC group consisted of 4 patients who died within the first 17 days postoperatively. Of these 4 patients, 2 patients died of right ventricular failure and multisystem organ failure on postoperative days 2 and 17. Another died on postoperative day 4 of a cerebrovascular accident, and fourth died of anoxic brain injury after ventricular fibrillation arrest on postoperative day 16. In all cases, the LVADs were functioning appropriately leading up to the time of death.

The patients undergoing CAVC had more severe AI at LVAD implant (mean score, 1.8 ± 1.4 vs 0.15 ± 43; $P < .01$). Immediately after LVAD placement, no patient in either group had more than mild AI. At the last imaging follow-up study (mean, 497 days; range, 37-1596 days), however, the severity of AI was significantly lower for the CAVC group (mean score, 0.27 ± 0.46) than for no-CAVC group (mean score, 0.78 ± 0.89; $P = .02$), resulting in a mean change in severity of AI of −1.5 compared with +0.6 in the no-CAVC group ($P < .01$). Furthermore, 18% of patients without CAVC experienced progression of AI to more than mild, but none in the CAVC group had greater than mild AI at the last follow-up examination ($P = .05$) (Table 3). During clinical follow-up, no reoperations for recurrent AI (after CAVC) were required in the present series, nor was a difference in late survival found between the 2 groups.

DISCUSSION

The principal finding of the present study was that CAVC with Park's stitch at LVAD implantation is effective in reducing AI and durable, with follow-up extending into 2 years. Additionally, an otherwise competent native aortic valve can develop AI over time with LVAD support.

AI in patients requiring LVAD therapy is not uncommon, as shown by the 15% prevalence in our series. The correction of AI at LVAD implantation has been shown to be associated with increased perioperative mortality in some,[8] but not all, studies.[4,9] The HeartMate II investigators reported their experience with concomitant cardiac operations at LVAD implantation. In their series, 47 patients underwent a valvular operation, 12 of whom underwent an aortic valve procedure, including a few patients (n = 8) who had the aortic valve patched closed