Acquired Cardiovascular Disease

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...
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. 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 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. In brief, after initiation of cardiopulmonary bypass, the aorta was cross-clamped 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 with Park’s stitch at LVAD implantation (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 –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 there 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, but not all, studies. 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.
or oversewn. The remainder had undergone aortic valve replacement. They reported an early mortality of 25% for patients undergoing an aortic valve procedure and theorized that it was, in part, owing to the need for cardioplegic arrest, with resultant myocardial dysfunction in already-marginal hearts. Studying those early deaths closely, sepsis and stroke was the cause of early death for 2 of the 3 patients; only 1 patient died of right ventricular failure. Of the early and late deaths, 4 of the 5 patients who died after an aortic valve procedure had undergone aortic valve replacement, not aortic valve closure. The reported cause of death in the remaining patient was sepsis.

In our series, we also observed greater early mortality among patients undergoing CAVC; however, the cause of death was also not attributable to the aortic valve procedure. Patients in the CAVC group were, on average, older and had more severe pre-existing comorbidities. The cause of death was right ventricular failure for only 1 of our 4 early deaths; the remaining 3 patients died of multisystem organ failure or hypoxic cerebral complications. Additionally, our 30-day survival for the CAVC group was not much different from

![Figure 1](image1.png)

**FIGURE 1.** Left, Central aortic regurgitation of native aortic valve. Middle, Central coaptation stitch of aortic valve performed at left ventricular assist device implantation. Right, Ejection of blood around centrally coapted aortic valve.

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**TABLE 1. Patient demographics**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Total patients (n = 123)</th>
<th>Aortic valve repair</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes (n = 18)</td>
<td>No (n = 105)</td>
<td></td>
</tr>
<tr>
<td>Age (y)</td>
<td>60 ± 13</td>
<td>66 ± 11</td>
<td>59 ± 14</td>
</tr>
<tr>
<td>Women (%)</td>
<td>16</td>
<td>17</td>
<td>16</td>
</tr>
<tr>
<td>White race (%)</td>
<td>93</td>
<td>88</td>
<td>93</td>
</tr>
<tr>
<td>Ischemic cardiomyopathy (%)</td>
<td>47</td>
<td>50</td>
<td>47</td>
</tr>
<tr>
<td>Hypertension (%)</td>
<td>34</td>
<td>22</td>
<td>36</td>
</tr>
<tr>
<td>Diabetes mellitus (n)</td>
<td>41 (33)</td>
<td>5 (28)</td>
<td>36 (34)</td>
</tr>
<tr>
<td>Renal insufficiency (n)</td>
<td>73 (60)</td>
<td>15 (83)</td>
<td>58 (55)</td>
</tr>
<tr>
<td>Atrial fibrillation (n)</td>
<td>37 (30)</td>
<td>7 (39)</td>
<td>30 (29)</td>
</tr>
<tr>
<td>Redo sternotomy (n)</td>
<td>54 (44)</td>
<td>11 (61)</td>
<td>43 (41)</td>
</tr>
<tr>
<td>Left ventricular ejection fraction (%)</td>
<td>20 ± 9.3</td>
<td>17 ± 5</td>
<td>20 ± 10</td>
</tr>
<tr>
<td>Destination therapy (n)</td>
<td>77 (63)</td>
<td>15 (83)</td>
<td>62 (60)</td>
</tr>
<tr>
<td>Severity of aortic regurgitation</td>
<td>—</td>
<td>1.8 ± 1.4</td>
<td>0.15 ± 0.43</td>
</tr>
<tr>
<td>(by intraoperative TEE)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proportion of AI greater than mild</td>
<td>100</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>(by intraoperative TEE)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BSA (cm²)</td>
<td>2.04 ± 0.24</td>
<td>1.96 ± 0.05</td>
<td>2.05 ± 0.24</td>
</tr>
</tbody>
</table>

Data presented as mean ± standard deviation, %, or n (%). TEE, Transesophageal echocardiography; AI, aortic insufficiency; BSA, body surface area.

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**TABLE 2. Intraoperative data**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Aortic valve repair</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes (n = 18)</td>
<td>No (n = 105)</td>
</tr>
<tr>
<td>Cardiopulmonary bypass time (min)</td>
<td>155 ± 61</td>
<td>108 ± 43</td>
</tr>
<tr>
<td>Aortic crossclamp time (min)</td>
<td>42 ± 25</td>
<td>41 ± 27*</td>
</tr>
<tr>
<td>Tricuspid valve procedure</td>
<td>13 (72)</td>
<td>52 (50)</td>
</tr>
<tr>
<td>Length of hospital stay (d)</td>
<td>26 ± 21</td>
<td>23 ± 16</td>
</tr>
<tr>
<td>30-d mortality</td>
<td>4 (22)</td>
<td>3 (3)</td>
</tr>
</tbody>
</table>

Data presented as mean ± standard deviation or n (%). *Of 105 patients, 14 underwent aortic crossclamping.
Table 3. Clinical course of aortic regurgitation

<table>
<thead>
<tr>
<th>Variable</th>
<th>Aortic valve repair</th>
<th>p</th>
<th>value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Echocardiographic follow-up (d)</td>
<td>441 ± 288</td>
<td>504 ± 354</td>
<td>NS</td>
</tr>
<tr>
<td>Severity of aortic regurgitation</td>
<td>0.27 ± 0.46</td>
<td>0.78 ± 0.89</td>
<td>.02</td>
</tr>
<tr>
<td>Patients with greater than mild</td>
<td>0/18 (0)</td>
<td>19/105 (18)</td>
<td>.05</td>
</tr>
<tr>
<td>regurgitation (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Data presented as mean ± standard deviation or n (%).

that reported by the HeartMate II investigators (79% vs 74%). However, it was inferior to the excellent survival outcome of 97% we observed for the patients without CAVC. Combined, these observations might support the theory that the long cardiopulmonary arrest times required to address AI (aortic valve replacement or CAVC) might contribute to early mortality; however, the shorter arrest times required for CAVC might be associated with proportionately less risk. To explore this possibility, we studied the effect of aortic crossclamping on 30-day mortality and found no association in our patient experience (P = NS; data not shown).

However, additional research is warranted in this area.

The development of native aortic valve regurgitation in patients with continuous flow LVADs is also not uncommon, demonstrated by the 18% incidence of greater than mild AI in our series. Numerous case reports and some case series have also been published describing the clinical problem of de novo AI during LVAD support. To date, 2 of our patients required reoperation because of the development of de novo AI after LVAD implant, and 1 died perioperatively. Reoperation for AI in patients receiving LVAD support can be very challenging. Recently, case reports have been published of an alternative percutaneous approach. It might prove very promising for those who develop delayed AI during LVAD support, but the experience is rather limited. Whether AI is an inevitable consequence of the constantly pressurized, closed aortic valve found during continuous flow LVAD support or whether this can be ameliorated by allowing the aortic valve to open intermittently is a topic for future investigation.

The limitations of the present study included those inherent to any retrospective clinical study; specifically, the small sample size and limited follow-up period. Additionally, the follow-up imaging was limited by serial studies performed under varying hemodynamic conditions (ie, volume status, antihypertensive regimen). Also, potential limitations exist to overseeing the aortic valve at LVAD implantation. One potential concern is that of cardiovascular collapse in the setting of LVAD pump failure due to complete pump thrombosis. One can speculate that this would be more likely to occur if the entire left ventricular outflow tract is occluded by either a thrombosed biologic valve or complete oversewing of the aortic valve. If LVAD failure were to occur in the setting of a completely closed aortic valve, no egress of blood from the ventricle would be possible, prompting sudden cardiovascular collapse. In contrast, if the aortic valve were only centrally closed, it is theoretically possible that blood could be ejected around the partial closure, allowing some cardiac output. Additionally, CAVC is contraindicated for patients in whom ventricular recovery is a possibility.

The present study was not a head-to-head comparison of the different techniques of aortic valve closure. Some philosophical differences could exist in addressing AI at LVAD implantation. Some investigators believe that the central coaptation stitch we use is inadequate because of 1 HeartMate I patient whose centrally plicated aortic valve became regurgitant and required repeat repair. This was not observed in our series, perhaps because our series only included continuous flow devices with different physiology and aortic valve-loading conditions. In our experience, all patients with CAVC were free from greater than mild AI at the last follow-up examination. Aortic valve replacement with a biologic aortic valve prosthesis or patch closure of the aorta are other alternatives but not our preference, because we believe the central coaptation stitch is quick and simple to perform, with well-demonstrated efficacy and durability.

Conclusions

Aortic valve repair using a central coaptation stitch is effective in reducing aortic regurgitation in patients with native aortic valve regurgitation at LVAD implantation. It has also proved to be durable in maintaining a competent aortic valve during follow-up extending beyond 2 years. It is our preferred approach to treating native aortic valve regurgitation at LVAD implantation owing to its simplicity, efficacy, and durability. Longer term follow-up is required to determine whether its use is warranted prophylactically in patients with no possibility of ventricular recovery and a long anticipated duration of LVAD support, such as permanent (destination) therapy to reduce the incidence of de novo or progression of mild aortic regurgitation after LVAD implantation.

References


