Utility of cardiac computed tomography for inflow cannula patency assessment and prediction of clinical outcome in patients with the HeartMate II left ventricular assist device

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Abstract

OBJECTIVES: Proper inflow cannula orientation during implantation of the HeartMate II (HMII) left ventricular assist device (LVAD) is important for optimal pump function. This article describes our experience with cardiac computed tomography (CCT) to evaluate inflow cannula patency and predict future adverse outcomes (AE) after HMII LVAD implantation.

METHODS: Ninety-three patients underwent HMII LVAD implantation for end-stage cardiomyopathy from January 2010 until March 2014. A total of 25 consecutive patients had CCT after the implantation; 3 patients were excluded from the analysis due to associated abnormality of the outflow graft. The 22 patients with CCT after HMII LVAD were censored for adverse events related to LVAD malfunction after HMII LVAD implantation. The maximum percentage of inflow cannula obstruction on CCT was recorded. We analysed the predictive value of CCT in addition to other clinical and diagnostic variables for future AEs.

RESULTS: Seven of the 22 patients (32%) experienced AEs after HMII LVAD implantation. The degree of inflow cannula obstruction was higher in the group of patients who experienced an AE (70 vs 14%; P < 0.001). Inflow cannula obstruction >30% showed excellent correlation with AE longitudinally based on receiver operating curve (0.829). The group with AEs more frequently experienced CHF symptoms (P = 0.054).

CONCLUSIONS: Inflow cannula obstruction >30% on CCT predicts future adverse events in patients with HMII LVAD; the need for surgical intervention in terms of LVAD exchange or urgent listing for heart transplantation should be considered in good surgical risk patients. Cardiac computed tomography should be considered routinely postoperatively in patients with HMII LVAD.

Keywords: HeartMateII • Left ventricular assist device • Inflow cannula • Obstruction

INTRODUCTION

An increasing number of patients with congestive heart failure (CHF) are currently supported with continuous flow left ventricular assist devices (LVADs). Despite survival improvement related to HeartMate II (HMII), several problems have arisen with the widespread use of the new generation circulatory support devices. Thrombus formation in the LVAD is associated with haemolysis, recurrent CHF symptoms, stroke and death [1–3].

Proper left ventricular assist inflow cannula alignment and patient compliance with anticoagulation therapy are intimately related to optimal device function. LVAD inflow cannula alignment assessment is based on non-invasive methods including chest radiograph and cardiac computed tomography (CCT) [4–7]. We present herein our experience with CCT to assess inflow cannula patency and predict future adverse outcomes after implantation of the HMII LVAD.

MATERIALS AND METHODS

From January 2010 until March 2014, 93 patients underwent HMII LVAD implantation for end-stage cardiomyopathy. All the patients were approached through a median sternotomy. Twenty-five patients had CCT. The other 68 patients had undergone heart transplant, or expired with HMII. Three patients who had partial
obstruction of the outflow graft due to kinking, migration of the bend relief component of the outflow graft or presence of thrombus were excluded from the analysis because the purpose was the investigation of inflow cannula obstruction-related adverse events (AEs).

Demographic and post-implantation information were extracted from the mechanical circulatory support and heart transplantation database and from individual electronic charts. Images were acquired on a GE 1.2.3 Healthcare VCT scanner (LightSpeed VCT; General Electric Healthcare; Milwaukee, WI, USA) (64 slice, electrocardiogram gated, 1.25 mm slice thickness). Following bolus infusion of 80–100 ml of intravenous contrast agent per a weight-based protocol (ISOVUE, 370 mg/ml; Bracco Diagnostic, Inc.; Monroe Township, NJ, USA) at 4 ml/s, contiguous helical axial images were obtained including the LVAD. The scans were acquired in retrospective mode such that 3D image volumes were obtained at multiple prescribed time intervals between QRS waves—specifically, 10 phases from 0 to 90% of the way through the cardiac cycle, allowing visualization of systolic and diastolic images.

A single reader evaluated each CCT, and graded inflow cannula stenosis when obstruction was present. Given the various observed 3D geometries of how myocardium or thrombus can crowd the flow of blood into the inflow cannula, stenosis was based on a stipulated conceptual model that focused on the 1 × 1 cm cylindrical volume of the left ventricular blood immediately adjacent to the inflow cannula. In this model, ‘normalcy’ required that there be no myocardium or thrombus bulging into this volume. If myocardium or thrombus did bulge into this volume, the percentage of the volume thereby effaced was considered the percentage stenosis. If the myocardium bulged into the ostium itself, stenosis was based on the area of the ostium that was obstructed. If the degree of stenosis varied through the cardiac cycle, stenosis was based on an estimated time-averaged stenosis (Figs. 1 and 2).

We censored the following adverse events longitudinally after HMII LVAD implantation: urgent listing for heart transplantation due to pump malfunctioning, urgent pump exchange due to pump malfunctioning and death-related to pump thrombosis. We recorded the presence of recurrent CHF symptoms, and the maximum degree of inflow cannula obstruction demonstrated on CCT after optimal volume management with diuresis and HMII speed adjustment.

Finally, an unbiased physician commented on the chest radiography LVAD alignment status including the pocket depth as well as the outflow and inflow cannula angle based on the criteria published by Taghavi et al. [7]. All the above variables were recorded at the time of the most recent follow-up or just prior to the index event. The group of patients without AEs was compared with the one with AEs with regard to the above variables. Categorical variables were presented as percentages, and continuous variables as median values with interquartile range. Differences in categorical variables between groups were analysed with the Fisher’s exact test, whereas differences in continuous variables were analysed with the Mann–Whitney U-test. The assumption of normal distribution was tested using a Shapiro–Wilks test. A P-value <0.1 was considered statistically significant. Institutional review board approval was obtained for this analysis.

The following variables were evaluated with univariate analysis: age, gender, diagnosis category (ischaemic versus non-ischaemic), presence of recurrent CHF symptoms despite optimal volume management and LVAD speed adjustment, assessment of proper LVAD alignment by independent reviewer on plain anterior–posterior chest radiograph projection and maximum degree of inflow cannula obstruction on CCT. Hazard ratios (HRs) and 95% confidence intervals (CIs) were calculated.

**RESULTS**

Twenty-two patients who had a CCT were included in this study. The majority of patients were men (n = 20, 91%). Eleven patients had ischaemic cardiomyopathy (50%). Non-ischaemic cardiomyopathy includes viral, postpartum, congenital, chemotherapy-induced and idiopathic aetiologies. Ten patients had an LVAD
placed as bridge to transplantation (46%). Seven patients (32%) experienced AEs due to pump malfunction: 2 required urgent pump exchange, 1 developed pump thrombosis leading to his demise, 4 were successfully transplanted after urgent listing. Two patients who had AEs expired close to the index event: one patient with pump thrombosis was allowed to expire after support withdrawal without any surgical intervention; the second patient died perioperatively from multiorgan system failure after pump exchange. In all 6 repeat surgical cases, the aperture of the inflow cannula appeared to have variable degree of obstruction intraoperatively by pannus, thrombus or myocardium.

The degree of inflow cannula obstruction on CCT was higher in the group of patients who experienced an AE due to pump malfunction (80 vs 10%; \( P < 0.001 \); Table 1). The group with AEs more frequently experienced CHF symptoms despite diuresis and pump speed adjustment (this difference reached statistical significance, \( P = 0.054 \)). Pump malalignment on chest radiograph judged by independent reviewer scores did not differ between the two study groups.

In the univariate analysis, recurrent CHF symptoms and degree of inflow cannula obstruction demonstrated with CCT were predictors of future adverse events (Table 2). Receiver operator curves were constructed to assess a cut-off inflow cannula obstruction percentage that corresponded to an AE longitudinally; this was excellent (0.829) for a 30% or greater inflow cannula obstruction.

**DISCUSSION**

Although the 2-year survival free of stroke and reoperation in heart failure patients has improved since the introduction of continuous flow LVAD HMII in 2008, this is not without risks. Thrombus formation in the LVAD can result in haemolysis, renal failure, stroke and death [2, 3, 8]. Thrombi can develop in the inflow cannula, the outflow graft or the pump proper of the LVAD. Proper inflow cannula alignment and anticoagulation are necessary to prevent pump thrombosis [7].

Several non-invasive diagnostic modalities are available to assess LVAD function [4–7, 9]. Plain chest radiograph can adequately demonstrate proper inflow cannula direction and adequate pump pocket creation, and has been shown to an independent predictor of future pump thrombosis [7] by other surgical groups. In our series, CCT appeared to be more sensitive modality than plain chest radiograph; the relatively small number of patients and the variable degree of subjectivity associated with reading the chest radiograph post HMII implant may explain our results.

Echocardiography is useful in identifying causes of mechanical malfunction in patients with older technology volume displacement LVADs; however, this modality is limited by the presence of artifacts. Recently, Estep et al. have proposed a simplified echocardiographic technique for detecting continuous flow LVAD malfunction due to pump thrombosis [5]. CCT is a useful modality, identifying malfunctioning LVAD cases due to inflow cannula malalignment and outflow obstruction; its sensitivity and specificity diagnosing pump thrombosis and inflow cannula malposition are 85 and 100%, respectively [10]. The only condition where the above modality lacks diagnostic sensitivity is isolated pump proper thrombosis. The diagnosis of pump proper thrombosis is made by excluding inflow and outflow graft thrombosis in the presence of markedly elevated markers of haemolysis.

Optimal left ventricular decompression in patients with LVAD is a dynamic process related to continuous flow LVAD speed, patient’s volume status and right ventricular contractility. Our policy is to obtain CCT after optimal LVAD speed adjustment based on echocardiography and LVAD pulsatility index. Following the above protocol, we eliminate cases of inflow cannula obstruction demonstrated on CCT purely related to suction events of the left ventricle and not due to true mechanical inflow cannula obstruction related to malalignment or thrombus.

Although it was suggested by CCT imaging that inflow cannula obstruction was caused by adjacent myocardium in all 6 surgical cases that underwent either LVAD exchange or urgent transplantation, there was pannus and variable degree of thrombus intraoperatively. We therefore believe that significant inflow cannula obstruction by myocardium due to malalignment inevitably leads to various degree of thrombosis.

Occasionally, HMII LVAD pump thrombosis is associated with partial or complete myocardial recovery despite sound surgical implant technique. We did not include any patients with myocardial recovery in our series.

As this is a retrospective analysis, the number of patients is small. Possible factors that may have biased the results may have not been included in this statistical analysis. Revalidation of CCT findings with a higher patient number may lead to firmer clinical treatment algorithms with regard to degree of inflow cannula obstruction in patients with continuous flow LVAD.

**Table 1:** Characteristics of both groups

<table>
<thead>
<tr>
<th>Variable</th>
<th>Adverse event (n = 7)</th>
<th>Uneventful course (n = 15)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male, n (%)</td>
<td>7 (100)</td>
<td>13 (87)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>ICMP, n (%)</td>
<td>3 (43)</td>
<td>8 (53)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>NICMP, n (%)</td>
<td>4 (57)</td>
<td>7 (47)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>BTT, n (%)</td>
<td>3 (43)</td>
<td>7 (47)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>DT, n (%)</td>
<td>4 (57)</td>
<td>8 (53)</td>
<td>&gt;0.999</td>
</tr>
<tr>
<td>Degree of IC obstruction, median (IQR)</td>
<td>80% (30–100%)</td>
<td>10% (0–20%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Refractory CHF symptoms, n (%)</td>
<td>4 (57)</td>
<td>2 (13)</td>
<td>0.054</td>
</tr>
<tr>
<td>Malalignment on CXR, n (%)</td>
<td>5 (71)</td>
<td>6 (40)</td>
<td>0.361</td>
</tr>
</tbody>
</table>

BTT: bridge to transplantation; CHF: congestive heart failure; CXR: chest radiograph; DT: destination therapy; IC: inflow cannula; ICMP: ischaemic cardiomyopathy; NICMP: non-ischaemic cardiomyopathy, IQR: interquartile range.

**Table 2:** Univariate adverse events analysis

<table>
<thead>
<tr>
<th>Variable</th>
<th>Hazard ratio</th>
<th>95% Confidence interval</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflow cannula obstruction</td>
<td>1.081</td>
<td>1.011–1.155</td>
<td>0.022</td>
</tr>
<tr>
<td>Recurrent CHF symptoms</td>
<td>8.667</td>
<td>1.049–71.569</td>
<td>0.045</td>
</tr>
</tbody>
</table>

CHF: congestive heart failure.
CONCLUSION

Inflow cannula malalignment in patients with HMII LVAD is associated with inflow cannula obstruction and future adverse events. CCT is an adjunct diagnostic tool that can demonstrate proper inflow cannula alignment and presence of various degree of obstruction. Patients with HMII LVAD with greater than 30% inflow cannula obstruction on CCT should be considered for pump exchange or urgent transplantation listing especially in the presence of refractory CHF symptoms. CCT should be considered postoperatively in every HMII LVAD patient.

Conflict of interest: none declared.

REFERENCES


