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Surgical Technique Influences HeartMate II Left Ventricular Assist Device Thrombosis

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Background. **Thrombosis of the HeartMate II (HM2 [Thoratec Corporation, Pleasanton, CA]) is a potentially devastating complication. While attention has been focused on anticoagulation strategies to prevent this complication, the impact of surgical technique has not been assessed.**

Methods. **Patients undergoing HM2 implantation at two institutions were reviewed. Pump thrombosis (PT) was defined as a clinical syndrome that included more than 30% elevation in pump power, more than 30% elevation in lactate dehydrogenase, and greater than 20% decrease in hemoglobin with the presence of thrombus in the HM2 stator or rotor, or both, at explant or autopsy. A blinded clinician reviewed dimensions and angles of the HM2 obtained from chest x-ray films. Patients demonstrating PT were compared with patients having normal function.**

Results. **Of the 49 patients reviewed, 11 (22.4%) displayed evidence of PT at a median of 42 days after HM2 implantation. Patient with PT had greater acute angulation of the HM2 inflow cannula immediately postoperatively (48.2 ± 6.8 versus 65.4 ± 9.2 degrees, $p < 0.001$) and after 30 days (50.1 ± 8.0 versus 65.1 ± 9.9 degrees, $p < 0.001$). Pump pocket depth was lower in the PT group immediately after HM2 implantation (107.0 ± 41.9 versus 144.3 ± 20.3 cm, $p < 0.001$) and after 30 days (86.0 ± 39.1 versus 113.1 ± 25.4 cm, $p = 0.02$). Patients with evidence of PT did not have a decrease in end-diastolic diameter (76 ± 9 versus 70 ± 15 mm, $p = 0.24$) whereas patients in the normal function group had effective remodeling of the left ventricle (70 ± 10 versus 56 ± 12 mm, $p = 0.01$).**

Conclusions. **Meticulous surgical technique, which necessitates creating an adequately sized pump pocket and appropriately directing the inflow cannula at the time of operation, may reduce the risk of PT.**

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Left ventricular assist device (LVAD) implantation has become the standard therapy for patients with end-stage heart failure refractory to medical therapy [1–5]. Hemolysis and pump thrombosis (PT) with thromboembolism is a recognized complication of LVADs [6, 7]. The advent of the continuous flow HeartMate II (HM2 [Thoratec Corporation, Pleasanton, CA]) has resulted in excellent clinical outcomes, and a lower rate of thromboembolic events and incidence of PT [3, 8, 9]. This has been predicated upon anticoagulation strategies, which minimize the risk of PT. Current guidelines recommend maintaining an international normalized ratio (INR) between 1.5 and 2.5 with a daily dose of at least 81 mg of aspirin [8, 9]. Recently, there has been an increasing awareness of hemolysis and PT. However, no study to date has examined the influence of surgical technique on the development of HM2 thrombosis. We hypothesized that meticulous surgical technique can mitigate the risk of PT.

Patients and Methods

After Institutional Review Board approval, adult patients undergoing HM2 implantation from August 2009 to May 2012 were retrospectively reviewed, spanning the period when the preclotted outflow graft was made commercially available. Laboratory data including lactate dehydrogenase, INR, and hemoglobin were collected prospectively.

We used anteroposterior chest roentgenogram (CXR) to assess for inflow cannula (IC) angulation and pump pocket (PP) depth because its clinically practical, measurements are easy to obtain, every patient undergoes numerous CXRs as part of routine care, and no added costs or studies are required. The CXRs obtained

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Abbreviations and Acronyms

CT	= computed tomography
CXR	= chest roentgenogram
HM2	= HeartMate II
IC	= inflow cannula
INR	= international normalized ratio
INTERMACS	= Interagency Registry for Mechanically Assisted Circulatory Support
LVAD	= left ventricular assist device
LVEDD	= left ventricular end-diastolic diameter
NF	= normal functioning
OC	= outflow cannula
PP	= pump pocket
PT	= pump thrombosis

immediately after implantation, 30 days after implantation, and finally before transplantation, death, or explant of LVAD were reviewed by a blinded clinician. This "final" CXR was taken a median of 183 days after implantation.

Measurements taken for the study are demonstrated in Figure 1A. The IC angle was the angle of the IC measured from the center of the LVAD rotor. The outflow cannula (OC) angle was the angle between the pump rotor and the outflow cannula. The PP depth was measured from the highest point of the diaphragm to the bottom of the pump rotor.

To eliminate CXRs where radiographic set-up error may contribute to rotation of the roentgenogram, and therefore to minimize distortion of the angles being assessed, we selected for CXRs in which the sternal wires were directly overlying the vertebrae and discarded films in which there was rotation greater than 2 mm. In addition, to further insulate the analysis from the effects of set-up error and rotation, all IC angle measurements were normalized to the outflow cannula (OC) angle. Since the OC is fixed to the body of the HM2 LVAD, this is a fixed structure with a known angle, and deviation from the known angle must connote radiographic set-up error and rotation. In addition, a validation set was performed in a subset of patients who underwent computed tomography (CT) scans as part of their clinical management. Using previously described techniques [10, 11] we corrected set-up error and rotation to human anthropomorphic measurements using digital techniques and then subjected appropriate coronal sections of thoracic CT scans to the same measurements being performed on anteroposterior CXR. These measurements were then compared with those obtained by CXR using Pearson correlation test. This showed a strong correlation between measurements of inflow cannula angle by CXR and CT scan (R value = 0.80) suggesting that set-up error and rotation did not contribute to distortion of angles measurement in this study.

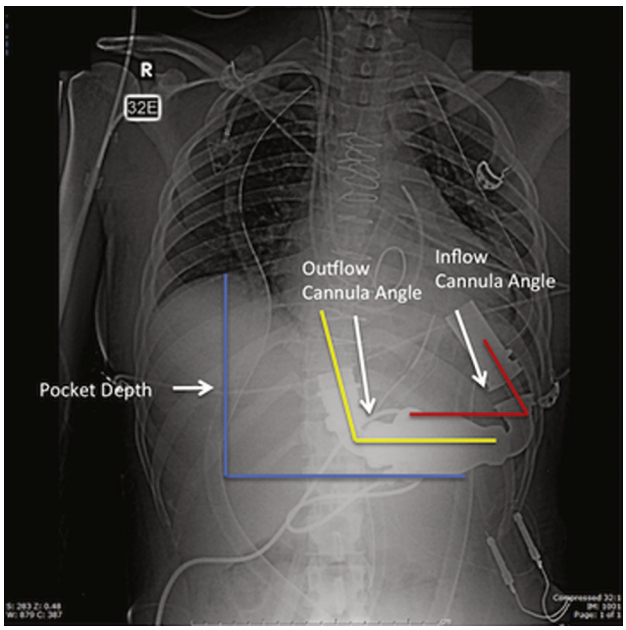

Fig 1. Measurements taken for study.

Patients with PT were compared with a control group of patients with normal functioning devices (NF group). The PT was defined as a clinical syndrome including more than 30% elevation in pump power, more than 30% elevation in lactate dehydrogenase, and greater than 20% decrease in hemoglobin and the presence of thrombus in the device at explant or autopsy, thus fulfilling the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) definition of PT, which is "thrombus documented to be present within the device or its conduits that result in or could potentially induce circulatory failure" [12].

Statistical Analysis

All data analyses were performed using SAS version 9.2 (SAS Institute, Cary, NC). Continuous variables are presented as mean ± SD or median, and categorical variables are reported as percentages of the total number of data points available for that field. Student's *t* test, and Fisher's exact test were used to analyze continuous and categorical variables. Receiver-operating characteristic curves were constructed to assess a cut-off point for inflow cannula angle that corresponds to PT. The cut-off point was calculated on the basis of the best trade-off value between sensitivity and specificity. Pearson correlation test was carried out to compare IC angle measurements made by CXR with those made by CT scan. Kaplan-Meier analysis was used to estimate survival and was compared with the log rank test.

Results

Baseline Patient Characteristics

Seventy-three patients underwent HM2 implantation during the study period. Twenty-four were excluded from the analysis because either all four criteria for PT were not present, patients did not fulfill requirements for the use of