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Continuous-flow left ventricular assist device exchange: Clinical outcomes

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BACKGROUND: A percentage of patients with a left ventricular assist device (LVAD) require device exchange. Although this is an important clinical entity, there are only a handful of relevant studies on this topic in the literature.

METHODS: From 2004 to 2012, 30 device exchanges (HeartMate II to HeartMate II) were performed. Since June 2011, we have employed the subcostal approach for device exchange if indicated. Sixteen patients underwent device exchange through a subcostal approach (S group), whereas 14 patients had devices exchanged through a full sternotomy (F group). Pre- and post-operative data were retrospectively reviewed.

RESULTS: There was no difference in baseline patient characteristics between the two groups. Overall, mean duration between primary surgery and device exchange was 425 ± 407 days. Surgical indications included device thrombus/hemolysis ($N = 19$), device malfunction ($N = 9$) and infection ($N = 2$). Cardiopulmonary bypass time was significantly shorter in the S group (S: 40 ± 23 minutes, F: 105 ± 84 minutes; $p < 0.05$), and post-operative bleeding within 24 hours after surgery was less in the S group (S: 362 ± 367 ml, F: 1,286 ± 971 ml; $p < 0.05$). Length of ICU stay was significantly shorter in the S group (S: 4.6 ± 1.8 days, F: 8.2 ± 4.9 days; $p < 0.05$). There was no difference in post-operative complications, except for prolonged intubation (F: $N = 6$ [43%], S: $N = 1$ [6.3%]; $p < 0.05$). There were 3 deaths in the F group and 0 in the S group, with no statistical difference ($p = 0.09$). Also, there was no significant difference in other outcomes, including transplantation, device explantation and ongoing LVAD support.

CONCLUSIONS: A subcostal approach may be preferred for HeartMate II device exchange if indicated.
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Left ventricular assist devices (LVADs) have emerged as an important strategy to treat refractory heart failure since the Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure (REMATCH) trial showed survival benefit in patients treated with the pulsatile LVAD (HeartMate XVE; Thoratec Corporation, Pleasanton, CA) as compared with maximal medical management.[1] A continuous-flow rotary-pump LVAD, the HeartMate II (Thoratec Corp.), is the second generation of the HeartMate LVAD, which showed superior survival and durability compared with the first generation.[2] The HeartMate II was approved for commercial use by the Food and Drug Administration in 2008 as a bridge to transplant and in 2010 as destination therapy after prospective, randomized

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trials.[2,3] To date, more than 10,000 HeartMate II LVADs have been implanted, and device exchange is required when complications arise such as device thrombus, infection or device malfunction. The incidence of HeartMate II device exchange varies from 1% to 9%, and seems to correlate with the goal of therapy (i.e., bridge to transplant or destination), as well as the era of surgery in which the implant was performed.[2–5]

In terms of surgical approaches for a HeartMate II device exchange, a median full sternotomy and a subcostal incision are generally accepted choices.[6] Since June 2011 we have employed a subcostal approach for device exchange when indicated. The purpose of this study was to summarize our experience with the surgical management of patients undergoing LVAD exchange and to determine surgical mortality and morbidity for each surgical approach.

Methods

This study was approved by the quality improvement review committee at Columbia University and the need for patient consent was waived. From April 2004 to December 2012, 269 HeartMate II devices were newly implanted at Columbia University Medical Center (CUMC), and 30 of these devices were exchanged (HeartMate II to HeartMate II). The data were retrospectively collected from our database and a review of medical records at CUMC. Overall, the mean follow-up period was 149 ± 227 days. The mean interval between the primary HeartMate II implantations and device exchanges was 425 ± 407 days. The primary HeartMate II implantations were performed as bridge to transplant in 21 patients and as destination therapy in 9 patients. Surgical indications for device exchange included device thrombus/hemolysis ($N = 19$), device malfunction ($N = 9$) and device infection ($N = 2$). The algorithm for diagnosing device thrombus at our institution was reported previously.[7] Four patients underwent two device exchanges each during this time period. Device thrombus was the sole indication for exchanges in half of the patients in this group, whereas the other half required exchange due to device thrombus in addition to device malfunction (i.e., driveline fracture).

Since June 2011, we have employed a subcostal approach for device exchange. Fourteen cases were performed with a median full sternotomy (F group) and 16 cases were with a subcostal approach (S group). The patients' demographics comparing the F and S groups are detailed in the Table 1. There was no significant difference in pre-operative parameters between the two groups.

Indication for a subcostal approach

We have preferably utilized the subcostal approach for device exchange since June 2011, unless contraindicated. The exclusion criteria from subcostal approach include the necessity to access the entire outflow graft (e.g., graft kinking, thrombus inside the graft and graft infection) and to perform concomitant cardiac procedures requiring a full sternotomy (e.g., aortic valve surgery due to aortic insufficiency). Computed tomography (CT) scan with contrast media is routinely performed pre-operatively to rule out inflow/outflow thrombosis. As a final confirmation, the inflow/outflow cannulas are closely evaluated with transesophageal echocardiography in the

Table 1 Patients' Pre-operative Demographics

Variable	Full sternotomy ($n = 14$)	Subcostal incision ($n = 16$)	p-value
Age (years)	59.5 ± 15.0	59.7 ± 10.8	0.969
Male:female	12:2	15:1	0.586
Diabetes mellitus	9 (64.3%)	4 (25.0%)	0.063
On insulin	4 (28.6%)	2 (12.5%)	0.378
Hypertension	9 (64.3%)	9 (56.3%)	0.722
Coronary artery disease	5 (35.7%)	8 (50.0%)	0.484
COPD	2 (14.3%)	2 (12.5%)	1.000
Chronic renal insufficiency (Cr > 2.0 mg/dl)	2 (14.3%)	5 (31.3%)	0.399
Dialysis	0 (0%)	0 (0%)	1.000
DT:BTT	5:9	4:12	0.694
Indications for the initial LVAD surgery			
Ischemic cardiomyopathy	5 (35.7%)	8 (50.0%)	0.484
Non-ischemic cardiomyopathy	9 (64.3%)	8 (50.0%)	0.484
Indications for the LVAD exchange			
Device thrombus	10 (71.4%)	9 (56.3%)	0.466
Device malfunction	3 (21.4%)	6 (37.5%)	0.440
Device infection	1 (7.1%)	1 (6.3%)	1.000
LVAD parameters			
Pulse index	4.9 ± 1.7	5.0 ± 1.4	0.881
Pump speed (rpm)	8,942 ± 332	9,211 ± 642	0.199
Interval between previous implant and device exchange (days)	407 ± 351	429 ± 461	0.886
Shock	1 (7.1%)	1 (6.3%)	1.000
Device stoppage	3 (21.4%)	3 (18.8%)	1.000
Sepsis	0 (0%)	0 (0%)	1.000

Continuous data are shown as mean ± standard deviation and categorical data as number (%). BTT, bridge to transplant; COPD, chronic obstructive pulmonary disease; Cr; serum creatinine; DT, destination therapy; LVAD, left ventricular assist device.