



A subcostal approach is favorable compared to sternotomy for left ventricular assist device exchange field of research: artificial heart (clinical)

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Abstract

This is a single-center retrospective study to summarize clinical outcomes of patients requiring surgical continuous-flow left ventricular assist device (HeartMate II) exchange. The patients who underwent HeartMate II exchange were divided into two groups either via a subcostal approach (SC group) or a full sternotomy (FS group). The exclusion criteria of a subcostal approach for device exchange included the presence of outflow graft obstruction, and/or the need for concomitant cardiac procedures. Among 277 consecutive patients who underwent HeartMate II implantation from July 2008 to December 2015, 25 patients (9.0%) required device exchange (SC group; $N=13$, FS group; $N=12$). The SC group, compared to the FS group, had a shorter operative time (200.6 ± 31.4 min vs 534.2 ± 123.9 min; $P < 0.001$), shorter cardiopulmonary bypass time (33.1 ± 22.0 min vs 151.5 ± 53.1 min; $P < 0.001$), fewer blood transfusion (0.31 ± 0.48 units vs 4.67 ± 3.65 units; $P = 0.002$). The SC group had lower incidence of postoperative prolonged intubation (> 24 h) (7.7% vs 90.9%, $P < 0.001$), tracheostomy (0.0% vs 41.7%, $P = 0.015$), acute kidney injury requiring dialysis (0.0% vs 33.3%, $P = 0.039$). In-hospital mortality was 0.0% (0/13) in the SC group and 16.7% (2/12) in the FS group ($P = 0.220$). In conclusion, a subcostal approach was associated with shorter operative time, fewer blood transfusions, and less postoperative complications, compared to full sternotomy. A subcostal approach, if feasible, is preferred for HeartMate II device exchange.

Keywords Left ventricular assist device · Thrombosis · Device exchange

Introduction

Left ventricular assist device (LVAD) has become one of gold standard treatments for end-stage heart failure in the last decade. However, LVAD-related complications are not totally preventable issues and significantly affect clinical outcomes. It includes device thrombosis, device infection, driveline fracture, and device malfunction which could potentially require a device exchange for a definite treatment.

Starling et al. reported an abrupt increase of incidence and early onset of device thrombosis since 2011 [1]. This might be caused by revision of definition of pump thrombosis, and possible underdiagnosing. Recent study reviewed the incidence for patients with LVAD failure requiring a device exchange or causing mortality during their follow-up ranged from 1.0 to 11.3% [2]. In the early era after HeartMate II was approved for clinical use, a full sternotomy approach was utilized for a device exchange regardless of which part of the device components (i.e. device body, outflow graft, inflow cuff, and/or all). It was a significantly invasive surgery associated with high mortality and morbidity rates. Recently, device exchange through a subcostal approach was reported by several investigators with excellent outcome [3–5]. They all showed that the advantage of subcostal approach included shorter operative time, shorter hospital stay, and lower complication rate compared to full sternotomy.

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In this study, we investigated the short- and mid-term outcomes of patients undergoing device exchange (HeartMate II) in our institution by comparing subcostal approach vs full sternotomy.

Methods

Study population

This is a single-center retrospective study. The study was approved by the University of Chicago Institutional Review Board, and the need for patient consent was waived. All the consecutive patients undergoing a LVAD implantation (HeartMate II, Thoratec Corp, Pleasanton, CA) through median full sternotomy from July 2008 to December 2015 in our institution were reviewed. All patients who had LVAD implantation received aspirin (81–325 mg) and Coumadin with a target Prothrombin Time and International Normalized Ratio of 2.0 to 3.0. Among them, subjects who underwent a device exchange during the follow-up were enrolled in this study. Indications of device exchange included device thrombosis, device infection, or any type of device malfunction. The cohort was divided into two groups; device exchange via a subcostal approach (SC group) or a full sternotomy (FS group). Since 2013, we preferably utilized a subcostal approach for a HeartMate II exchange. The exclusion criteria of a subcostal approach included the presence of outflow graft obstruction, and/or the need of concomitant cardiac procedures. Pre- and postoperative data were retrospectively reviewed to assess clinical outcomes and compared the SC group with the FS group.

Surgical technique

Device exchange via a subcostal approach was performed as previously described [3]. Briefly, a reverse J-shaped incision or a chevron incision is made from the xiphoid process toward the left mid-clavicular line passing through 1–2 inches below the left costal arch. If necessary, the incision can be extended toward the left and the costal cartilage can be divided for better exposure (rib-cross incision) [7]. Once adequate device exposure is obtained, systemic heparinization is given and cardiopulmonary bypass (CPB) is established by femoral artery and vein cannulation. Then, the bend relief is detached from the device body and the outflow graft is clamped. The patient is positioned in deep Trendelenburg position. The device body with or without the inflow cannula is removed, and the drive-line is cut in the operating field. To ensure there is no obstructive thromboembolic material left inside the outflow/inflow tracts, sufficient backward and forward blood flow should be confirmed. A new device body is put in place and the new drive-line is passed

through a new tunnel out to the skin. De-airing is performed by making a hole in the outflow graft using an 18-gauge needle. CPB is then weaned off as the new LVAD is initiated. After administration of a dose of protamine to reverse heparin, the femoral cannulas are removed followed by the routine closure of incisions in layers.

Device exchanges via a full re-sternotomy was performed with the standard technique. After CPB initiation with central or peripheral cannulation, all component of the device was replaced including apex cuff, inflow cannula, device body, and outflow graft with the exception of situations where the surgeon left the apex cuff as is.

Clinical outcome parameters

The primary interests are postoperative complications including prolonged ventilation, re-intubation, tracheostomy, surgical site infection, gastrointestinal bleeding, acute kidney injury requiring dialysis, stroke, re-exploration for bleeding, and in-hospital mortality. Other outcomes of interest are postoperative catecholamine use, nitric oxide use, length of ICU stay, length of hospital stay, 1-year cumulative survival rate, recurrent device thrombosis, and any event requiring re-intervention.

Statistical analysis

Continuous variables are expressed as mean \pm standard deviation, or median [interquartile range (IQR)], and were compared using the Student's *t* test or Mann–Whitney *U* test depending on their distribution. Categorical and sequential variables are expressed as the number and percentage of patients, and were compared by the chi-square test or Fisher's exact test, as appropriate. One-year survival rate, freedom from recurrent device thrombosis, and freedom from re-intervention of the two groups were analyzed with Kaplan–Meier analysis with a log-rank analysis. A *P* value of less than 0.05 was considered to be statistically significant. The statistical analyses were conducted using IBM SPSS 22.00 (IBM, Inc, Chicago, IL, USA).

Results

Patient population

The patient baseline characteristics are detailed in Table 1. Among 277 consecutive patients who underwent LVAD implantation, 25 patients (9.0%) required device exchange during the follow-up period (21 male, median age of 51 years old). Device exchange was performed via a subcostal approach (SC group, *N* = 13), or a full sternotomy (FS group, *N* = 12). There were no statistical differences between

Table 1 Preoperative patients' characteristics

Variables	All patients (N=25)	SC group (N=13)	FS group (N=12)	P value
Age, year	51 [46–66]	54 [49–69]	46 [34–62]	0.022
Male, n (%)	21 (84.0)	9 (69.2)	12 (100)	0.096
Body surface area, m ²	2.20 [2.05–2.40]	2.20 [2.05–2.20]	2.40 [1.90–2.85]	0.098
Body mass index, kg/m ²	32.2 [27.9–37.2]	31.9 [29.1–35.6]	33.2 [27.1–44.3]	0.852
Hypertension, n (%)	22 (88.0)	12 (92.3)	10 (83.3)	0.593
Dyslipidemia, n (%)	11 (44.0)	6 (46.2)	5 (41.7)	0.821
Diabetes mellitus, n (%)	10 (40.0)	5 (38.5)	5 (41.7)	1
Chronic renal failure, n (%)	11 (44.0)	7 (53.8)	4 (33.3)	0.302
COPD, n (%)	11 (44.0)	7 (53.8)	4 (33.3)	0.302
Ischemic heart disease, n (%)	9 (36.0)	6 (46.2)	3 (25.0)	0.411
History of cerebrovascular accident, n (%)	3 (12.0)	1 (7.7)	2 (16.7)	0.593
History of gastrointestinal bleeding	8 (32.0)	6 (46.2)	2 (16.7)	0.202
Device thrombosis, n (%)	23 (92.0)	13 (100)	10 (83.3)	0.22
Ramp test positive, n (%)	14 (56.0)	9 (69.2)	5 (41.7)	0.165
AKI by LVAD dysfunction, n (%)	11 (44.0)	4 (30.8)	7 (58.3)	0.165
Acute stroke by LVAD thrombus, n (%)	2 (8.0)	1 (7.7)	1 (8.3)	1
Preoperative LDH, IU/L	1235 [946–2503]	1148 [901–2308]	2130 [959–2588]	0.32
Interval from LVAD implantation, days	255 [94–503]	210 [107–330]	379 [59–833]	0.376

Continuous variables are presented as median [interquartile range]

SC subcostal, FS full sternotomy, COPD chronic obstructive pulmonary disease, LDH lactate dehydrogenase, AKI acute kidney injury, LVAD left ventricular assist device

the SC group and the FS group in preoperative patients' characteristics, except for age. Surgical indications included device thrombosis (92.0%, $N=23$), device malfunction (4.2%, $N=1$), and device infection (4.2%, $N=1$). Surgical intervention for device thrombosis was chosen when refractory to medical therapy, end-organ impairment, and hemodynamic instability [6]. There were 11 patients (44.0%) with chronic renal failure (defined as serum creatinine greater than 1.5 before the device failure), and 11 patients (44.0%) had preoperative acute kidney injury (defined as an increase in serum creatinine greater than 2 times baseline) likely due to significant hemolysis. The median interval from LVAD implantation to device exchange was 255 [IQR 94–503] days.

Intra-operative outcomes

Intra-operative data was summarized in Table 2. Device exchange was successfully performed in all cases. The SC group, compared to the FS group, had a shorter operative time, shorter cardiopulmonary bypass time, and fewer blood transfusion use. In the FS group, 3 patients underwent HeartMate II-to-Heartware HVAD (HeartWare International, Framingham, Massachusetts) exchange. There were 4 emergency cases (one in the SC group, 3 in the FS group), otherwise urgent cases. Concomitant procedure was performed in 5 patients in the FS group, which included aortic

valve repair/replacement in 3, mitral valve repair in 1, and tricuspid valve repair in 2. One case was converted from subcostal approach to full sternotomy because of outflow graft kinking/obstruction which was found during the case.

Postoperative outcomes

Post-operative outcomes were summarized in Table 3. The SC group, compared to the FS group, had a lower incidence of postoperative prolonged ventilation (> 24 h), acute kidney injury requiring dialysis and tracheostomy. No patient newly required dialysis in the SC group, but 4 patients in the FS group (16.0%). There were no differences in postoperative catecholamine use between two groups. Nitric oxide was used less frequently in the SC group compared to the FS group (0.0% vs 50.0%, $P=0.005$). Right ventricular assist device was not utilized in the SC group, and 1 patient in the FS group without significant difference ($P=0.480$). Regarding surgical site infection, there were one groin infection in the SC group (7.7%), while there were 2 mediastinitis in the FS group (16.7%). One patient in the SC group had a subcostal wound dehiscence requiring a wound revision. The length of ICU and hospital stay were significantly longer in the FS group compared to the SC group. Overall In-hospital mortality was 8.0% (2/25). In-hospital mortality in the SC group was 0.0% (0/13) and 16.7% (2/12) in the FS group with no statistical difference ($P=0.220$).

Table 2 Intraoperative data

Variables	All patients (N=25)	SC group (N=13)	FS group (N=12)	P value
Operation time, min	235 [191–532]	201 [182–213]	540 [438–583]	<0.001*
Cardiopulmonary bypass time, min	39 [25–156]	25 [24–35]	156 [126–180]	<0.001*
Heart Mate II to Heart Mate II	21 (84.0)	13 (100)	8 (66.7)	0.039*
Heart Mate II to Heart Ware	4 (16.0)	0 (0)	4 (33.3)	0.039*
Emergency, n (%)	4 (16.0)	1 (7.7)	3 (25.0)	0.322
Blood transfusion, n (%)	18 (72.0)	6 (46.2)	12 (100)	0.005*
Red blood cell 1 unit, n (%)	4 (16.0)	4 (30.8)	0 (0.0)	0.096
Red blood cell 2 units, n (%)	1 (4.0)	0 (0.0)	1 (8.3)	0.48
Red blood cell 3 units, n (%)	1 (4.0)	0 (0.0)	1 (8.3)	0.48
Red blood cell > 4 units, n (%)	7 (28.0)	0 (0.0)	5 (58.3)	0.002*
Red blood cell, units	2.40 ± 3.34	0.31 ± 0.48	4.67 ± 3.65	<0.001*
Fresh frozen plasma, units	3.56 ± 4.34	0.31 ± 0.63	7.08 ± 3.82	<0.001*
Platelet, units	1.96 ± 2.37	0.15 ± 0.55	3.92 ± 1.98	<0.001*
Concomitant procedure, n (%)	5 (20.0)	0 (0)	5 (41.7)	0.015*
Visible thrombus, n (%)	17 (68.0)	9 (69.2)	8 (66.7)	1

Continuous variables are presented as median [interquartile range], or mean ± standard deviation

SC subcostal, FS full sternotomy

*P value less than 0.05

Table 3 Postoperative outcomes

Variables	All patients (N=25)	SC group (N=13)	FS group (N=12)	P value
Prolonged ventilation (> 24 h), n (%)	11 (45.8)	1 (7.7)	10 (90.9)	<0.001*
Ventilation time, h	20 [6–46]	7 [3–18]	60 [32–191]	<0.001*
Re-intubation	3 (12.5)	0 (0.0)	3 (27.3)	0.082
Tracheostomy, n (%)	5 (20.0)	0 (0.0)	5 (41.7)	0.015*
Postoperative nitric oxide use, n (%)	6 (24.0)	0 (0.0)	6 (50.0)	0.005*
Postoperative dobutamine use, n (%)	24 (96.0)	13 (100)	11 (91.7)	0.48
Postoperative epinephrine use, n (%)	18 (72.0)	9 (69.2)	9 (75.0)	1
Postoperative milrinon use, n (%)	1 (4.0)	0 (0.0)	1 (8.3)	0.48
RVAD use, n (%)	1 (4.0)	0 (0.0)	1 (8.3)	0.48
Surgical site infection, n (%)	3 (12.0)	1 (7.7)	2 (16.7)	0.593
Gastrointestinal bleeding, n (%)	0 (0.0)	0 (0.0)	0 (0.0)	-
Acute kidney injury requiring dialysis, n (%)	4 (16.0)	0 (0.0)	4 (33.3)	0.039*
Stroke, n (%)	1 (4.0)	0 (0.0)	1 (8.3)	0.48
Re-exploration for bleeding, n (%)	2 (8.0)	1 (7.7)	1 (8.3)	1
Length of ICU stay, h	120 [72–168]	72 [48–120]	168 [120–504]	0.002*
Length of hospital stay, days	15 [10–26]	14 [10–18]	26 [13–35]	0.039*
In-hospital mortality, n (%)	2 (8.0)	0 (0.0)	2 (16.7)	0.22

Continuous variables are presented as median [interquartile range]

SC subcostal, FS full sternotomy, RVAD right ventricular assist device, ICU intensive care unit

*P value less than 0.05

Sub-comparative analysis between the SC group and the FS group without concomitant procedure or Heart Mate II-to-HeartWare HVAD exchange (FS' group; 5 cases) in perioperative outcomes was conducted (Table 4). There were no statistical differences between the SC and the FS'

group in preoperative patients' characteristics, except for older age in the SC group. Operation time, cardiopulmonary bypass time, rate of red blood cell transfusion use > 4 units, rate of postoperative prolonged ventilation (> 24 h)

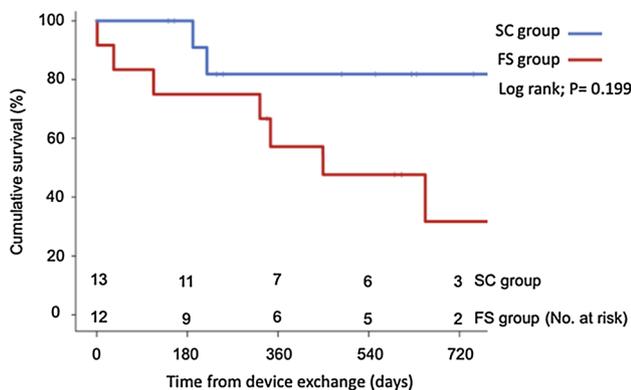
Table 4 Sub-comparative analysis between the SC group vs FS group without concomitant procedure or Heart Mate II-to-HeartWare HVAD exchange (FS' group)

Variables	SC group (N=13)	FS' group (N=5)	P value
Age, years	54 [49–69]	45 [29–56]	0.014*
Operation time, min	201 [182–213]	444 [432–530]	0.004*
Cardiopulmonary bypass time, min	25 [24–35]	127 [55–160]	0.003*
Red blood cell > 4 units, n (%)	0 (0.0)	3 (60.0)	0.012*
Prolonged ventilation (> 24 h), n (%)	1 (7.7)	5 (100)	0.002*
Postoperative nitric oxide use, n (%)	0 (0.0)	2 (40.0)	0.065
Acute kidney injury requiring dialysis, n (%)	0 (0.0)	2 (40.0)	0.065
Length of ICU stay, h	72 [48–120]	168 [126–426]	0.010*
Length of hospital stay, days	14 [10–18]	27 [13–34]	0.202
In-hospital mortality, n (%)	0 (0.0)	1 (20.0)	0.278

Continuous variables are presented as median [interquartile range]

SC subcostal, FS full sternotomy, FS' full sternotomy without concomitant procedure or Heart Mate II to HeartWare exchange, ICU intensive care unit

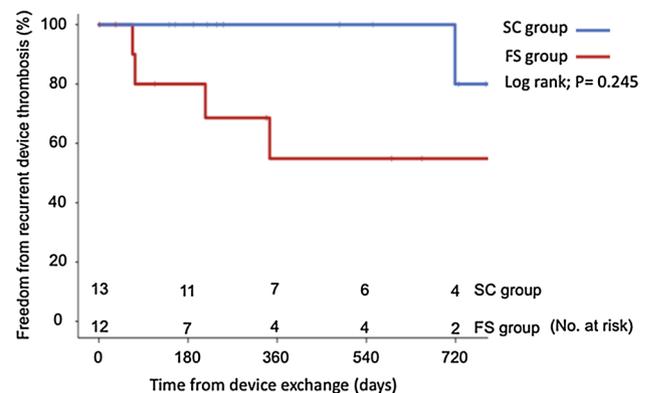
*P value less than 0.05

**Fig. 1** Survival rate of the subcostal approach group and the full sternotomy group by Kaplan–Meier analysis

and length of ICU stay were statistically lower in the SC group compared to the FS' group.

Mid-term outcomes

Mean follow-up time was 520.5 ± 375.9 days after device exchange. One patient received heart transplantation 338 days after device exchange in the FS group. Kaplan–Meier analysis showed overall 1- and 2-year survival rate were 68.9%, and 53.0%. One-year survival rates of the SC group and the FS group did not statistically differ (81.8% vs 57.1%, $P=0.199$) (Fig. 1). There were 10 mortality during the follow-up (SC: $N=3$, FS: $N=7$). The cause of death included congestive heart failure in 6 patients, cerebrovascular accident in 2, sepsis in 1, and gastrointestinal bleeding in 1. Six patients (24.0%) had a recurrent device thrombosis, and two patients (8.0%) required re-intervention (i.e. 2nd time device exchange via subcostal approach $N=1$, via full sternotomy $N=1$) during the follow-up period. There

**Fig. 2** Freedom from recurrent device thrombosis of the subcostal approach group and the full sternotomy group by Kaplan–Meier analysis

was no significant difference in the two groups in terms of freedom from recurrent device thrombosis and freedom from re-intervention in Kaplan–Meier analysis (Figs. 2, 3).

Discussion

In this study, we investigated clinical outcomes of HeartMate II device exchange by comparing subcostal approach and full sternotomy. Subcostal approach was associated with shorter operative time, lower incidence of postoperative complications (prolonged ventilation, acute kidney injury requiring dialysis, and tracheostomy), fewer blood transfusion use, and shorter hospital stay compared to full sternotomy. One-year survival rate was comparable between two groups.

As the number of patients undergoing LVAD support has been increasing, we encounter more LVAD-related complications. Among them, device thrombosis is one of

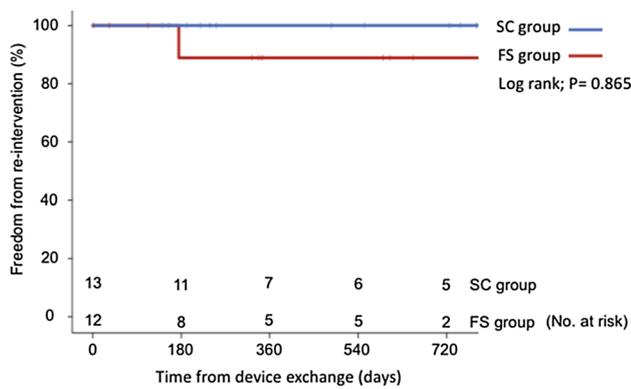


Fig. 3 Freedom from re-intervention of the subcostal approach group and the full sternotomy group by Kaplan–Meier analysis

the difficult properties to treat and potentially life-threatening. Early surgical intervention is recommended by several investigators reporting improved outcomes over medical treatment. Allison et al. reported that device exchange provided better outcomes than intensification of antithrombotic therapy which is associated with increased incidence of cerebrovascular accident and death [8]. Stulak et al. showed medical therapy for device thrombosis was associated with low success rate and greater risk of hemorrhagic stroke and death compared to early surgical exchange [9]. It is well documented that medical therapy including interventional/systemic thrombolysis is effective with device thrombosis for HeartWare HVAD over surgical exchange [10, 11]. However, Oezpeker et al. mentioned in their report that difference of pump design and mechanism might affect the efficacy of thrombolysis therapy, and in general, thrombolysis therapy for axial flow pumps (i.e. HeartMate II) is considered less effective compared to for centrifugal pumps (i.e. Heartware HVAD) [12].

While surgical device exchange is an effective treatment strategy, it is still considered surgically challenging especially with a full re-sternotomy because of sick patient population in general and the complexity of surgery in nature. Device exchange via a subcostal approach was reported in 1998 for the first time [13]. In our institution, we have preferably utilized a subcostal approach for HeartMate II device exchange when feasible since 2013. The advantages of a subcostal approach for device exchange were demonstrated by several investigators. Ota et al. reported surgical outcomes of a series of 30 device exchange cases. They concluded that group of subcostal approach had shorter operative time, less postoperative bleeding, shorter length of ICU stay, and less incidence of prolonged ventilation [3]. Behzad et al. reviewed 17 patients who underwent device exchange either subcostal or full sternotomy, and concluded the outcomes of subcostal approach were shorter operative time, lower rate of re-exploration for bleeding, fewer transfused blood products, and shorter hospital stay

[4]. Those findings are consistent with our study. As for the mid-term outcome of patients undergoing a device exchange with a subcostal approach, Allison et al. reported that 1-year survival rate is better in subcostal approach (100%) than full sternotomy (63%) in 28 device exchange cases [5]. In their study, the recurrent device thrombosis around 30% regardless of surgical approaches. In the present study, there was no statistical difference between subcostal approach and full sternotomy in 1-year cumulative survival rate. We had 6 device exchange cases via a full sternotomy before employing a subcostal approach, and the 30-day mortality of those patients was 17%. Retrospectively, 4 cases out of 6 could have done via a subcostal approach with our current surgical indication. It is important to note that while a subcostal approach provides several advantages over a full sternotomy, it does not allow to access to the entire outflow graft and it is difficult/impossible to revise the inflow cannula angle relative to the heart in case necessary.

In terms of postoperative complications, subcostal approach was associated with lower risk of acute kidney injury requiring dialysis, tracheostomy, and shorter ICU and hospital stay in the present study. While catecholamine was postoperatively used in most cases regardless of approaches, nitric oxide treatment for right side heart support was required more frequently in the full sternotomy cases. Right heart failure is one of the most devastating LVAD-related complications, and it occurs approximately 20–30% of patients undergoing LVAD implantation [14, 15]. Left ventricular distention due to unloading failure changes the geometry of the right ventricle, resulting in tricuspid regurgitation and subsequent right ventricular dysfunction [16]. It is well known that cardiopulmonary bypass affects right heart function by inviting pulmonary hypertension/edema. Theoretically, it would be critical to save CPB time to prevent right heart dysfunction especially in vulnerable patients such as end-stage heart failure with LVAD support [17]. Perioperative blood transfusion use is also detected as a predictor of right heart failure during LVAD implantation [18]. We believe that shorter CPB time and less blood transfusion use might have contributed to the improved outcome in patients with a subcostal approach where no one required nitric oxide treatment. In conclusion, a subcostal approach was associated with shorter operative time, fewer blood transfusions, and decreased incidence of postoperative complications, compared to full sternotomy. A subcostal approach, if feasible, is preferred for HeartMate II device exchange compared to full sternotomy.

Limitations

There are limitations that should be addressed. First, it is a single-center, non-randomized, retrospective study. Second, the study involved a relatively small number of patients, and

concern regarding statistical power might be raised. Third, this study included the patient population who required a device exchange with concomitant cardiac procedure(s) or exchange to different device (HeartWare) via a full sternotomy where a subcostal approach would not have been indicated. Those procedure(s) would have given extra invasiveness to those patients that might have affected their outcomes. Fourth, the difference of principal diagnosis between the groups might have driven the difference of outcomes. Finally, the subcostal approach has applied since 2013, therefore, 4 of 6 cases which could have been applied with subcostal approach were performed with full sternotomy approach before 2013.

Compliance with ethical standards

Conflict of interest Dr Valluvan Jeevanandam discloses that he receives consultant fees from Abbott. Dr Nir Uriel discloses that he receives consultant fees and grant supports from Abbott, and Medtronic.

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