Non-cardiac surgery in patients with continuous-flow left ventricular assist devices: a single institutional experience

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ABSTRACT

With improvements in life expectancy for patients with continuous-flow left ventricular assist devices (LVADs), non-cardiac surgeons will increasingly encounter surgical problems in this population. 209 patients underwent LVAD placement between 10/1/2007 and 6/1/2015 at a single institution. Survival was compared between patients who had non-cardiac surgery (NCS) during the initial LVAD implantation hospitalization (n=36) and those who had NCS only in subsequent hospitalizations (n=33). Postoperative complication rates were examined. Index admission NCS was associated with lower 5-year survival compared with subsequent admission NCS (27.1% vs 39.4%, p=0.017). In subsequent admissions, the risks of bleeding and infectious complications were the same for elective or urgent NCS, but the risk of death was higher in the urgent surgery group. We conclude that elective NCS can be performed with low risk of death or LVAD dysfunction after sufficient recovery of patients from LVAD implantation.

Significance of this study

What is already known about this subject?

- In 2013, more than 2400 continuous-flow left ventricular assist devices (LVADs) were implanted in the USA with 80% 1-year survival and 70% 2-year survival while maintained on a LVAD.
- Acute care surgical problems are increasingly more common in patients with LVADs as the life expectancy of this population increases.
- Perioperative bleeding is a frequently reported complication of non-cardiac surgery (NCS) in patients with LVADs.

What are the new findings?

- 5-year cumulative survival was the same in LVAD patients who had NCS compared with LVAD patients who did not have additional non-cardiac surgery.
- Among the LVAD patients who did have non-cardiac surgery, however, the 5-year survival was significantly worse in those patients who required the operation during the index LVAD hospitalization.
- Perioperative bleeding may be higher in the LVAD population.
- No patient developed LVAD thrombosis following NCS.

How might these results change the focus of research or clinical practice?

- This study enhances the existing literature on NCS in continuous-flow LVAD patients by analyzing the outcomes of procedures by their timing and their urgency. We found that after sufficient recovery of patients from LVAD implantation, elective non-cardiac surgery can be performed with low risk of death or LVAD dysfunction. Given this knowledge, stable LVAD patients with select surgical problems such as hernia or carotid stenosis should undergo surgery rather than often inadequate medical management.

INTRODUCTION

Heart failure has become widespread in the USA, with an estimated 5.1 million Americans suffering from this condition.[1] Despite maximal medical therapy, 10% of these patients will progress to end-stage failure with heart transplant or ventricular assist device implant as the only viable long-term options. Unfortunately, the supply of donor hearts remains severely limited, making transplantation a treatment available only for a highly select subset of patients.

Left ventricular assist devices (LVADs) have been present since the 1960s in several highly experimental iterations. After extensive research, they became available for a larger population of patients in the late 1980s as a means to hemodynamically stabilize and bridge patients to heart transplant. Since their inception, several different generations of devices have been developed with increasing sophistication. The success of LVADs in the bridge-to-transplant population paved the way for these devices to be used as destination

therapy in patients deemed ineligible for heart transplants. Initially built to generate pulsatile blood flow, the newest LVADs use a centrifugal or axial flow pump to provide continuous non-pulsatile flow in the body. In 2013, more than 2400 continuous-flow LVADs were implanted in the USA with 80% 1-year survival and 70% 2-year survival while maintained on an LVAD.[2]

As LVAD use grows, it is inevitable that non-cardiac surgeons in numerous specialties will be called on to operate on these patients, both during the initial implant hospitalization and after hospital discharge. With the expanded use of LVADs and the improvement in life expectancy and quality of life in LVAD patients, non-cardiac surgeons will increasingly be confronted with elective and urgent surgical problems in these individuals. Some of these patients, seeking treatment for common surgical conditions such as cholecystitis, appendicitis, hernia or fracture, will inevitably present to surgeons or centers without extensive LVAD experience. Given the need for specialized care in these inherently high-risk patients with complex hemodynamics and hardware, perioperative management is evolving, and the role of elective or semielective non-cardiac surgery (NCS) is unclear. Until now, there have been only a few studies with small sample sizes that begin to examine this topic. The purpose of this study is to describe our large single-center experience with NCS in durable continuous-flow LVAD patients to delineate both principles of perioperative management and outcomes.

METHODS

We retrospectively reviewed the charts for all patients who received continuous-flow LVADs between October 1, 2007 and June 1, 2015 at our institution. Continuous-flow LVADs included HeartMate II (Thoratec Corp, Pleasanton, California, USA), HeartWare HVAD (Heartware International, Framingham, Massachusetts, USA), and VentrAssist (Ventracor, Canberra, Australia). Patients implanted with either a temporary device such as the CentriMag (Thoratec, Pleasanton, California, USA), a pulsatile device, or a total artificial heart (Syncardia, Tucson, Arizona, USA) were excluded from the study, as these were used as short-term bridges to early heart transplant. Only NCS performed while the patient had an LVAD in place were included, and NCS performed after heart transplant or cardiac recovery with LVAD explant were excluded. Mediastinal explorations and electrophysiological procedures after an LVAD implant were also excluded.

Patients were grouped by those who had NCS during the same admission as an LVAD implant and those who only had NCS during a subsequent admission. Since a primary focus of our paper is to study the management and outcomes of NCS problems that might present to surgeons and/or centers with little or no LVAD experience, we selected the procedures that were performed at a subsequent admission for further analysis. These operations were classified as urgent or elective based on the nature and the indication of the procedures. The primary outcome of this study was 5-year mortality after LVAD placement. The complications after non-cardiac operations performed at an admission subsequent to an LVAD implant were examined as secondary outcomes. This study was approved by the Institutional Review Board on Human Subject Research at the Hospital of the University of Pennsylvania.

All LVAD patients were accompanied to the operating room by an LVAD coordinator. A cardiac anesthesiologist was available at the time of every procedure, but was not necessarily the primary anesthesiologist involved in a given case. Cardiac surgeons were not directly involved in non-cardiac cases except in some tracheostomies but were available on-call. For elective operations, patients were bridged from Coumadin to heparin preoperatively, with a goal partial thromboplastin time (PTT) typically ranging from 40 to 60, and an international normalized ratio (INR) typically <2.0. In addition to standard hemodynamic monitoring, patients had an arterial line placed preoperatively. Patients did not typically have Swan-Ganz catheters placed. During abdominal procedures, the LVAD driveline was prepped out of the field, and the surgeon took particular care not to expose or injure the driveline with the incision. In some cases, laparoscopic port placement had to be adjusted to avoid damaging the driveline or pump pocket housing the LVAD, in the case of the HeartMate II. During laparoscopic cases, a gentle pneumoperitoneum was created with very gradual insufflation of the abdominal cavity under scrupulous hemodynamic observation.

Patient characteristics were compared using Student's t-test for continuous variables and χ^2 test for categorical variables. Median values were compared with the Mann-Whitney test. Survival curves were compared with the log-rank test. All analyses were performed using Stata V.14 (College Station, Texas, USA). A p value <0.05 was considered statistically significant.

RESULTS

From October 1, 2007 to June 1, 2015, a total of 209 patients underwent placement of a continuous-flow LVAD. Of these, 169 (81%) patients received a HeartMate II, 35 (17%) received a HeartWare HVAD, and 5 (2%) received a VentrAssist. Sixty-nine (33.0%) patients underwent 136 non-cardiac procedures after LVAD implantation. Of these 69 patients, 25 had NCS only during the index admission after their LVAD placement, 11 had NCS during both the index and subsequent admissions, and 33 had NCS only during subsequent admissions. These patient groups are displayed schematically in figure 1. The baseline characteristics of LVAD patients who had at least one NCS (n=69) and those who did not (n=140) are compared in table 1. The group who underwent NCS comprised slightly older patients, more of whom received an LVAD for destination therapy rather than as a bridge to transplant, perhaps an indication of sicker patients or a reflection of longer duration of LVAD therapy.

Nearly all surgical disciplines were represented in the non-cardiac procedures performed with general surgery procedures (n=55, 40.4%) being the largest group followed by plastic surgery (n=26, 19.1%), vascular surgery (n=20, 14.7%), urology (n=10, 7.4%), neurosurgery (n=8, 5.9%), orthopedic surgery (n=6, 4.4%), and thoracic surgery (n=2, 1.5%). Of these procedures, 58 (42.6%) were performed in the same admission during which the LVAD was implanted. Seventy-eight procedures (57.4%) were performed during an admission subsequent to the hospitalization in which the LVAD was placed.

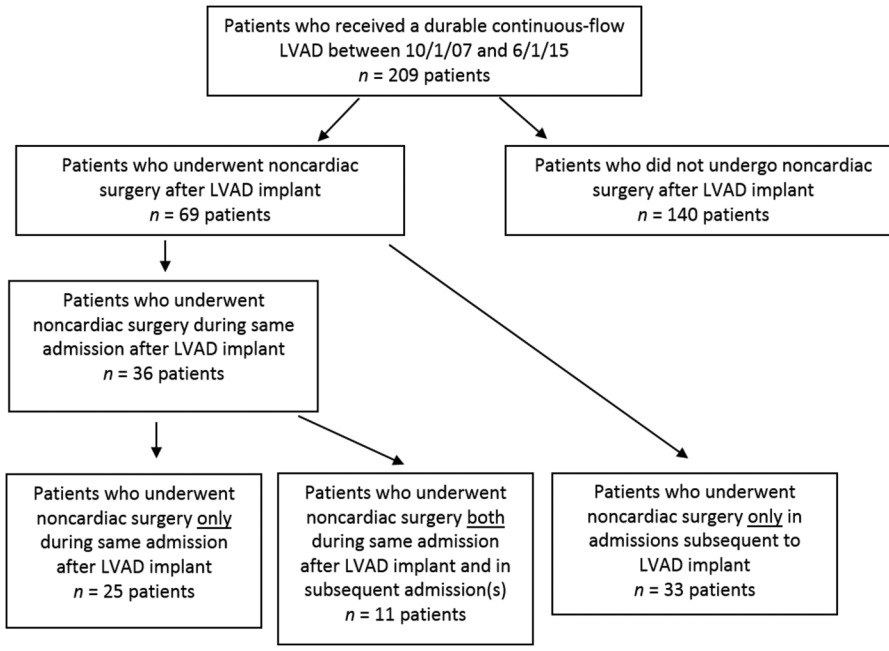

Figure 1 Schematic of patient groups. LVAD, left ventricular assist device.

Figure 2 shows the Kaplan-Meier 5-year survival of patients with LVADs who did not undergo NCS (n=140) versus those who had NCS in the same admission (n=36) and those who had NCS in a subsequent admission (n=33) to the LVAD implant. Cumulative 5-year survival was no different between no NCS patients (n=140) compared with all patients who underwent NCS (n=69), log-rank p=0.350 or between no NCS patients (n=140) compared with subsequent admission NCS patients (n=33), log-rank p=0.567. However, a difference in survival was seen between no NCS patients (n=140) and same admission NCS patients (n=36), log-rank p=0.027 and between same and subsequent admission NCS patients, p=0.018.

The distribution of time from LVAD implant to first NCS is shown in figure 3. The majority of NCS performed in the same admission as an LVAD implant occurred within the first 30 days, and the majority of those performed in a subsequent admission occurred within the first year. To summarize, median time from LVAD implant to same admission NCS was 15 and 329 days for subsequent admission NCS (p<0.001, table 2). Median length of stay after same admission NCS was 28 vs 12 days for subsequent admission NCS (p<0.001). Median survival after LVAD placement was 180 days for patients who had NCS in the same admission compared with 1737 days for patients who had NCS in a subsequent admission (p=0.018).

Of the 78 subsequent admission NCS procedures, 35 were elective in nature, and 43 were urgent. Overall, there were 29 complications in these 78 procedures, which can be broken down into five categories: infection, bleeding, wound breakdown, death, and other (table 3). There were no deaths in the elective operations group but five deaths occurred in the urgent operations group after three neurosurgery procedures, an endovascular repair of a ruptured abdominal aortic aneurysm, and a small bowel resection for obstruction. After elective surgery, the complication category 'other' comprised a transient episode of aphasia and confusion after carotid artery stenting, air leak after lobectomy, and a bowel obstruction after hysterectomy. In the urgent surgery group, the category 'other' included an accidental tracheostomy decannulation after tracheostomy insertion and a non-viable musculocutaneous flap for wound coverage.

When comparing anticoagulation between the elective and the urgent surgery groups, the mean PTT was equivalent on the day of surgery and first postoperative day. However, the mean INR in the elective group was lower than that in the urgent group both on the day of surgery and on postoperative day 1 (p=0.037 and p=0.034, respectively). Nevertheless, the number of bleeding complications was no different between the groups. Though we had several bleeding complications, there were no perioperative thromboembolic complications other than the possible transient ischemic attack after elective carotid artery stenting. Notably, no LVAD thrombosis was attributed to the non-cardiac procedures.

DISCUSSION

We examined the outcomes and complications of NCS in patient with continuous-flow LVADs at our institution. This retrospective review is one of the largest studies examining NCS in patients maintained on mechanical circulatory support. Of the 209 patients in our institution who had implantation of a continuous-flow LVAD over almost 8 years, nearly one-third subsequently underwent an NCS. These procedures encompass virtually all surgical disciplines with general surgery being the largest specialty represented. In our series, the overall complication rate of the 78 subsequent admission NCS was 37%, the majority of which were bleeding (n=11, 14.1%) and infection (n=6, 7.7%). No patient developed LVAD thrombosis following a non-cardiac procedure.

Table 1 Baseline characteristics

	Patients without non-cardiac procedures (n=140)	Patients with ≥1 non-cardiac procedure (n=69)	p Value
Age	54.6±15.9 years	59.5±13.9 years	0.032
Male gender	110 (79%)	55 (80%)	1.000
Race			0.669
Caucasian	69 (49%)	31 (45%)	
African-American	31 (22%)	13(19%)	
Hispanic	1 (1%)	2 (3%)	
Asian	1 (1%)	0	
Unknown	37 (26%)	22 (32%)	
Other	1 (1%)	1 (1%)	
Body mass index	28.5±6.5	28.3±6.4	0.814
Pre-existing conditions			
Coronary artery disease	70 (50%)	44 (64%)	0.077
Pulmonary hypertension	50 (36%)	25 (36%)	0.877
Chronic obstructive pulmonary disease	19 (14%)	12 (17%)	0.535
Diabetes	61 (44%)	36 (52%)	0.235
Hypertension	80 (57%)	46 (67%)	0.285
Dyslipidemia	83 (59%)	48 (70%)	0.122
Stroke	11 (8%)	10 (14%)	0.150
Renal failure requiring hemodialysis	6 (4%)	8 (12%)	0.074
Previous myocardial infarction	46 (33%)	25 (36%)	0.755
Heart failure etiology			0.313
Ischemic	60 (43%)	40 (58%)	
Idiopathic	61 (44%)	23 (33%)	
Congenital	1 (1%)	0	
Viral	2 (1%)	0	
Peripartum	3 (2%)	2 (3%)	
Alcoholic	1 (1%)	0	
Myocarditis	4 (3%)	0	
Cancer-induced	4 (3%)	1 (1%)	
Valvular	1 (1%)	2 (3%)	
LVAD indication			0.010
Bridge to transplant	61 (44%)	18 (26%)	
Bridge to decision	13 (9%)	6 (9%)	
Destination therapy	60 (43%)	45 (65%)	
Recovery	6 (4%)	0	

LVAD, left ventricular assist device.

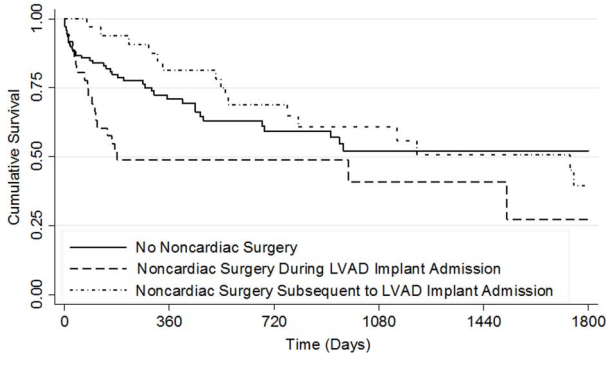

Figure 2 Kaplan-Meier survival curves from time of LVAD implant for patients who had no non-cardiac procedure, patients who had a same admission NCS, and patients who had a subsequent admission NCS. LVAD, left ventricular assist device; NCS, non-cardiac surgery.

Notably, the cumulative 5-year survival of all patients who underwent an NCS after an LVAD implant was not different from those who did not require a non-cardiac operation. Among the LVAD patients who did have NCS, however, the 5-year survival was significantly worse in those patients who required the operation during the index LVAD hospitalization. Additional surgery soon after LVAD placement most likely represents a salvage operation in sicker patients and is correlated with worse outcomes, as expected. Our analysis also shows that elective procedures performed after recovery of the patient from LVAD implant is associated with minimal risk of death or LVAD dysfunction. Given the increasing utility of LVADs for long-term treatment, it is likely that more non-cardiac surgeons and centers with limited LVAD experience will soon be called on to treat this growing population of complex patients. Our experience shows that LVAD patients who require NCS are typically older with a higher proportion with

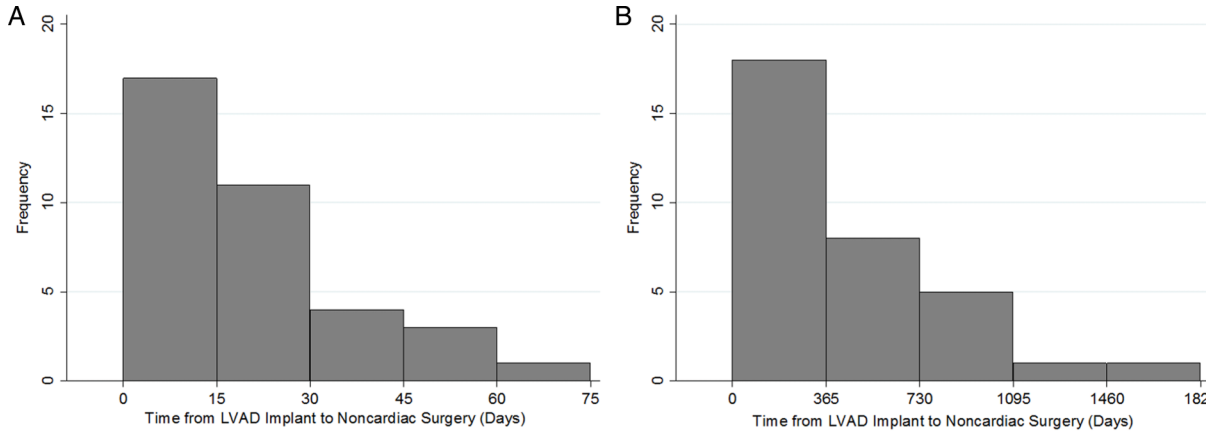

Figure 3 Distribution of time from LVAD implantation to first NCS for (A) patients who had a same admission NCS and (B) patients who had a subsequent admission NCS. LVAD, left ventricular assist device; NCS, non-cardiac surgery.

Table 2 Temporal characteristics of same versus subsequent admission NCS

	Same admission NCS	Subsequent admission NCS	p Value
Number of patients	36	33	–
Median time from LVAD to NCS (days)	15 (10–28)	329 (149–582)	<0.001
Median length of stay after NCS (days)	28 (17–46)	12 (8–17)	<0.001
Median survival after LVAD implant (days)	180 95% CI at least 105	1737 95% CI at least 563	0.018

Values in parentheses for median time from LVAD to NCS and median length of stay after NCS represent the IQR around the median. Upper limit of 95% CI for median survival cannot be calculated based on the available data.
LVAD, left ventricular assist device; NCS, non-cardiac surgery.

Table 3 Postoperative complications and anticoagulation level in urgent versus elective subsequent admission non-cardiac operations

	Elective	Urgent	p Value
Number of operations	35	43	–
Median length of stay after NCS (Days)	8 (5–13)	12 (6–16)	0.162
Complications			
Infection, n (%)	3 (8.6%)	3 (7.0%)	0.793
Bleeding, n (%)	6 (17.1%)	5 (11.6%)	0.486
Wound breakdown, n (%)	2 (5.7%)	0	0.112
Death, n (%)	0	5 (11.6%)	0.037
Other, n (%)	3 (8.6%)	2 (4.7%)	0.482
Anticoagulation			
Day of surgery PTT (sec)	38.6±12.6	39.0±20.1	0.915
Day of surgery INR	1.48±0.43	1.73±0.57	0.037
Postoperative day 1 PTT (s)	40.0±11.2	46.3±26.4	0.181
Postoperative day 1 INR	1.39±0.32	1.61±0.45	0.034

Values in parentheses represent the IQR around the median for length of stay. Plus–minus values denote mean±SD.
INR, international normalized ratio; NCS, non-cardiac surgery; PTT, partial thromboplastin time.

pre-existing coronary artery disease on destination therapy. Therefore, the risks and benefits of each procedure must be carefully evaluated in this population, and non-essential operations should not be performed in this population with decreased life expectancy.

Interest in NCS in LVAD patients first appeared in the literature in the 1990s. In this early period, the majority of the retrospective studies on this subject were by default conducted in patients with first-generation pulsatile LVADs.[3–5] Now, the majority of LVADs placed are continuous-flow devices. Some studies have been published on the topic of NCS in LVAD patients, though they include fewer patients than our series. The largest study to date by Arnaoutakis *et al*[6] consisted of 47 patients who underwent 67 procedures. However, nearly one-third of the patients studied had a pulsatile LVAD, the HeartMate XVE. The authors recognized that acute care surgical problems are common in LVAD patients but are not associated with adverse outcomes in HeartMate II patients, though the risk of postoperative infection, the most common complication, was 24%. In comparison, our infection rate was 7.7% in operations performed in subsequent admissions to LVAD placement. Interestingly, Arnaoutakis *et al* concluded that HeartMate II patients could be maintained off anticoagulation for several months with a low risk of thrombosis, though recent data showing a rise in pump thrombosis brings this practice into question.[7] In our study, no pump thrombosis was experienced though the mean INR of patients undergoing elective NCS was 1.48. In 2012, Bhat *et al*[8] reviewed 36 patients who underwent 63 NCS and concluded that though patients with LVADs may require more transfusions than patients not on mechanical circulatory support, they can undergo NCS with minimal intraoperative complications. In line with the existing literature, the authors found that LVAD dysfunction or thrombosis was rare; however, the Kaplan-Meier curve based on the timing of surgery—whether emergent or elective—showed a large disadvantage in the patients undergoing emergent surgery ($p<0.0001$).

Perioperative bleeding is a frequently reported complication of NCS in LVAD patients as reported in most institutional series. Morgan *et al*[9] reviewed 20 patients with

HeartMate II who underwent 25 non-laparoscopic procedures. Though all but three of these operations were elective, nine procedures (36%) required transfusions. Similarly, Garatti *et al*[10] found that 10 of their 11 patients who underwent an NCS required blood transfusions. Though Brown *et al*[11] also reported a high incidence of bleeding during NCS, this complication did not predict worse long-term outcomes as the 1-year survival was similar between patients who underwent NCS and those who did not. Therefore, holding or partially reversing anticoagulation in the immediate preoperative period is a key consideration when planning procedures in this population. Our general practice for anticoagulation management after NCS is the resumption of a heparin infusion as early as 6–12 hours after surgery, or when deemed appropriate by the surgeon. We titrate HeartMate II patients to a PTT goal of 40–50 s and HeartWare patients to a goal of 50–60 s. Both types of LVAD patients are transitioned to Coumadin with an INR goal of 2.3–2.8 once the highest risk of postsurgical bleeding has passed. With this management strategy for subsequent admission surgeries, our bleeding-related complication rate was 14.1%. Of note, in our study, no exploratory laparotomy was performed for gastrointestinal bleeding, which is frequently observed in patients with HeartMate II LVADs.[12 13]

The surgeries described here represent a wide spectrum of operations, and a detailed list of all procedures is found in the online supplementary appendix. In the LVAD population, tracheostomies are one of the most common procedures performed under general anesthesia. McKellar *et al*[14] reviewed a series of non-cardiac procedures in a sample of 99 patients of which 80 had a continuous-flow LVAD. Of the 28 procedures performed, more than half were tracheostomies. Taghavi *et al*[15] reported 14 tracheostomies in their series of 47 NCS in LVAD patients. We also saw a large number of tracheostomies and tracheostomy-related procedures in our post-LVAD population—25 of 136 procedures (18%)—with the vast majority performed during the index hospitalization.

Our study enhances the existing literature on NCS in continuous-flow LVAD patients by analyzing the outcomes of procedures by their timing and their urgency. We found that patients who undergo additional NCS early postoperatively after their LVAD placement have worse outcomes than those who have had a chance to recover from their LVAD procedure. Similar to other studies on this topic, a limitation of our study remains the small sample size of patients who undergo NCS procedures. Our single-center experience can be augmented by pooling data from other centers with extensive LVAD experience. In addition, our experience is not entirely generalizable to all surgical centers across the nation. Given our robust mechanical circulatory support programme, every LVAD patient who required NCS was accompanied to the OR with an LVAD coordinator with extensive knowledge of the function and design of the devices. Nevertheless, we report the largest series on NCS in which most surgical disciplines are represented in an effort to show that a broad array of procedures can be performed in LVAD patients with a low risk of LVAD dysfunction.

CONCLUSION

After sufficient recovery of patients from implantation of continuous-flow LVADs, elective NCS can be performed with low risk of death or LVAD dysfunction. However, perioperative complication rates, most notably bleeding, may be higher in this population, and only procedures with benefits that significantly outweigh the risks should be performed. To achieve the best outcomes when performing NCS on LVAD patients, we recommend transfer of the patient to an LVAD center. However, in the event that transfer cannot be achieved secondary to patient, resource, or environmental factors, and procedures cannot be delayed, the surgeon should:

- Bridge anticoagulation from Coumadin (or other long-acting agents) to heparin for INR <2.0 and PTT 40–60.
- Contact the LVAD coordinator and cardiac surgeon on call at the nearest LVAD center and maintain an open line of communication.
- Ensure the intraoperative placement of an arterial line for hemodynamic monitoring.
- Plan the surgical incision or laparoscopic port placement to avoid the LVAD hardware and driveline.
- Carefully ensure meticulous hemostasis.
- Resume anticoagulation early postoperatively as soon as the period with highest risk of bleeding has passed.

Contributors This study was conceived by DTD, who continued to provide conceptual guidance throughout the project. Data collection was performed by CWC and OS, and data analysis was a joint endeavor by CWC and KRD. PA and MAA contributed their expertise in management of patients with left ventricular assist devices. The manuscript was written by CWC and OS commented on by all authors.

Competing interests None declared.

Patient consent Obtained.

Ethics approval University of Pennsylvania Institutional Review Board (Protocol #817143).

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