Outcomes of Abdominal Surgery in Patients With Mechanical Ventricular Assist Devices: A Multi-Institutional Study

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Scholarly Report Title: Outcomes of Abdominal Surgery in Patients With Mechanical Ventricular Assist Devices: A Multi-Institutional Study

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Objective: The aim of this study was to examine the outcomes of elective and emergent abdominal operations performed in end-stage heart failure patients supported with ventricular assist devices (VADs).

Summary of Background Data: With the growing volume of end-stage heart failure patients receiving VADs, an increasing number of these patients require surgery for noncardiac pathology. There is a paucity of studies on the safety of abdominal operations in this population.

Methods: We performed a retrospective chart review across 3 hospitals of patients with VADs who underwent abdominal surgeries between 2003 and 2015. We used Chi-square, Fisher exact, and Mann-Whitney U tests for comparison of elective and emergent cases.

Results: Fifty-seven patients underwent 63 operations, of which 23 operations were elective, 24 were emergent, and 16 were emergently performed in the same admission as VAD placement and analyzed separately. Patients undergoing elective versus emergent procedures had similar comorbidities (Charlson score 2.9 vs 3.0). 43% versus 32% of patients had VADs as a destination therapy. Although perioperative anticoagulation approach was variable, holding warfarin and starting heparin/enoxaparin/bivalirudin bridge was most common (65% vs 54%). Although 2-fold higher in the emergent group (50 vs 100 mL, P = 0.06), median estimated blood loss was low. Postoperative bleeding requiring transfusion was not very common (13% vs 8%), whereas rate of ischemic cerebrovascular accident (4% each) and venous thromboembolism was low (0% vs 13%, P = 0.23). Thirty-day mortality rate was 4% versus 17%, P = 0.19.

Conclusion: VAD patients have an acceptable risk profile for abdominal surgery.

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Key abbreviations:

VAD = ventricular assist device

LVAD = left ventricular assist device

Student Role and Team

I joined this project in May 2016, when authors Kiely, Kimbrell, Asban, Kelley, and Melnitchouk had created a preliminary database of patients with ventricular assist devices (VADs) and heart transplants who had undergone abdominal surgery at Tufts, Brigham & Women's and Massachusetts General Hospital. The project was initially conceived as a study of outcomes of colorectal operations in VAD versus heart transplants. However, after Dr. Melnitchouk and I reviewed the literature further, we found that there was a paucity of studies on outcomes of non-cardiac operations in VAD patients. Together, Dr. Melnitchouk and I redesigned the study to examine the outcomes of abdominal operations in order to better address the concerns of general surgeons working with VAD patients.

I then performed majority of the chart review for the patients from Brigham & Women's and Massachusetts General Hospital, for both post-operative outcomes and peri-operative anti-coagulation management for all patients with ventricular assist devices. Drs. Kiely and Asban collected analogous data from Tufts. I independently analyzed the data with input from Dr. Melnitchouk regarding table and figure design, and subsequently wrote the initial draft of the manuscript in April 2017. Drs. Kiely and Melnitchouk contributed to multiple manuscript revisions. Drs. Bleday and Davids also contributed guidance to the overall project. Dr. Melnitchouk and I managed submission to Annals of Surgery.

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Appendix

Leung KM, Kiely MX, Kimbrell A, Asban A, Kelley R, Bleday R, David J, and Melnitchouk N. Outcomes of abdominal surgery in patients with mechanical ventricular assist devices. *Annals of Surgery.* 2017 Sep 6. doi: 10.1097/SLA.0000000000002513.

Outcomes of Abdominal Surgery in Patients With Mechanical Ventricular Assist Devices

A Multi-Institutional Study

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Results: Fifty-seven patients underwent 63 operations, of which 23 operations were elective, 24 were emergent, and 16 were emergently performed in the same admission as VAD placement and analyzed separately. Patients undergoing elective *versus* emergent procedures had similar comorbidities (Charlson score 2.9 vs 3.0). 43% *versus* 32% of patients had VADs as a destination therapy. Although perioperative anticoagulation approach was variable, holding warfarin and starting heparin/enoxaparin/bivalirudin bridge was most common (65% vs 54%). Although 2-fold higher in the emergent group (50 vs 100 mL, $P = 0.06$), median estimated blood loss was low. Postoperative bleeding requiring transfusion was not very common (13% vs 8%), whereas rate of ischemic cerebrovascular accident (4% each) and venous thromboembolism was low (0% vs 13%, $P = 0.23$). Thirty-day mortality rate was 4% *versus* 17%, $P = 0.19$.

Conclusion: VAD patients have an acceptable risk profile for abdominal surgery.

Keywords: abdominal operations, heart failure, noncardiac operations, ventricular assist devices

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There is an increasing number of patients with end-stage heart failure; as the population ages, the rate of metabolic syndrome rises, and the treatment modalities improve. Mechanical ventricular assist devices (VADs) are being used more frequently in this group of patients, either as a bridge to transplant (BTT) or destination therapy (DT). Modern mechanical ventricular support devices have greatly extended this population's lifespan, with some patients living well over 2 to 4 years after device implantation, whether they are implanted as a bridge to eventual cardiac transplantation[1] or as DT.[2]

As survival improves, there is a growing population of patients with ventricular support devices who require surgical care for noncardiac issues, whether for elective or urgent operations.[3] The operative and perioperative management of the patients who require abdominal operations is complicated. Usually, cardiac anesthesiologist and perfusionists are needed to manage the patient intraoperatively. Furthermore, the driveline to the VAD device is tunneled in the abdominal wall, so the surgeon must be vigilant about preventing injury to it and avoiding contamination. Additionally, anticoagulation management in these patients requires balancing the risk of thrombotic and bleeding complications. International normalized ratio (INR) values <2.0 can lead to an increase in the rate of pump thrombosis formation and ischemic (embolic) stroke in these patients.[4] At the same time, most patients with continuous flow VADs develop an acquired von-Willebrand syndrome[5] and some degree of red blood cell hemolysis from mechanical shear stress. Limited studies exist on the safety and outcomes of abdominal operations in these patients.[6] We sought to perform a multicenter retrospective review of the patients with ventricular assist devices who underwent abdominal operations to examine the postoperative outcomes.

METHODS

Study Population and Data Collection

We performed a retrospective chart review of 468 patients with ventricular assist devices and identified 57 patients who underwent 63 abdominal operations between 2003 and 2015 at 3 major tertiary referral centers in Boston, MA (Brigham and Women's Hospital, Massachusetts General Hospital, and Tufts Medical Center). We collected preoperative data on patient demographics, comorbidities, laboratory values, type, purpose, and time since implantation of VAD, method of anticoagulation/bridging, and urgency of the case (emergent at the time of VAD placement, emergent, and elective). Charlson comorbidity score was calculated for each patient at the time of the abdominal operation. Abdominal surgeries were classified as exploratory laparotomy alone, hernia repair (diaphragmatic, incisional, inguinal, umbilical), hepatobiliary (cholecystectomy, liver biopsy), gastrointestinal (appendectomy, bowel resection), wound, other general surgery (bariatric, splenectomy, peritoneal dialysis catheter, percutaneous gastrostomies/jejunostomies), or urologic operations. Our postoperative variables were length of stay, complications, reoperation, and 30-day mortality. For patients who underwent multiple unrelated abdominal operations, these were included as separate cases. The study was approved by the respective institutional review boards.

Study Description

We performed a multi-institutional study of patients with end-stage heart failure supported by mechanical ventricular assist devices and the outcomes of abdominal operations in this population.

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The authors report no conflicts of interest.

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TABLE 1. Baseline Patient Characteristics

Variable	Elective (n = 21)	Emergent (n = 22)
Male sex, no. (%)	16 (76)	19 (86)
Age, y, median	66 (54–70.5)	59 (49–65)
BMI, median	28 (24–31.5)	28 (27–31)
Ischemic cardiomyopathy, no. (%)	11 (52)	9 (41)
Charlson Comorbidity Score (mean ± SD)	2.9 ± 1.1	3.0 ± 1.2
Comorbidities, number (%)		
Type 2 diabetes mellitus	8 (38)	10 (45)
Hypertension	13 (62)	11 (50)
Chronic kidney disease	6 (29)	10 (45)
Arrhythmia, including atrial fibrillation	10 (48)	11 (50)
History of cerebrovascular accident	5 (24)	1 (5)
History of thromboembolic event	2 (10)	1 (5)
History of heparin-induced thrombocytopenia	5 (24)	2 (9)
VAD as destination therapy, no. (%)	9 (43)	7 (32)
Ventricular support device, no. (%)		
Thoratec VAD (as LVAD)	3 (14)	0 (0)
Heartmate XVE	1 (5)	2 (9)
Heartmate II	10 (48)	12 (52)
Heartware	3 (14)	3 (13)
Other LVAD	2 (10)	2 (9)
Thoratec PVAD (as BiVAD)	2 (10)	2 (9)
Syncardia TAH	0 (0)	1 (4)

Data are reported as number (% of patients), mean ± standard deviation, or median (interquartile range).
BMI indicates body mass index; SD, standard deviation; TAH, total artificial heart.

TABLE 2. Pre-operative Characteristics

Variable	Elective (n = 21)	Emergent (n = 22)	P
No. of surgical cases	23	24	
Creatinine, mg/dL, median	1.06 (0.87–1.20)	1.21 (0.91–1.67)	0.16
Hematocrit, median	33.9 (29.25–38.75)	29.1 (22.65–35.7)	0.19
Platelet count, $\times 10^3$ cells/μL, median	219 (162.5–270.5)	187 (97.25–238.5)	0.13
INR, median	1.4 (1.2–1.75)	1.55 (1.3–1.93)	0.27
aPTT, s, median	39.5 (37–43.6)	41.3 (35.3–54)	0.54
Anti-coagulation regimen, no. (%)			
Warfarin continued	2 (9)	0 (0)	
Warfarin held 5 days, resumed post-op	6 (26)	n/a	—
Warfarin held emergently, resumed without bridge	n/a	7 (29)	
Warfarin held with bridge	15 (65)	13 (54)	
Heparin	10 (43)	13 (54)	
Enoxaparin	1 (4)	0 (0)	
Bivalirudin	4 (17)	4 (17)	

Data are reported as number (% of cases) or median (interquartile range).
aPTT indicates activated thromboplastin time; n/a, not applicable.

Statistical Analysis

Two-tailed Chi-square or Fisher exact test was used to compare categorical variables as appropriate. The two-tailed Mann-Whitney *U* test was used to analyze continuous variables. Statistical significance was defined as $P < 0.05$.

RESULTS

A total of 57 patients underwent 63 operations, of which 23 were elective, 24 were emergent, and 16 were emergent operations performed in the immediate postoperative period after VAD placement and thus analyzed separately. Two patients underwent both elective and emergent operations during unrelated admissions.

Demographics

There was no significant difference in Charlson Comorbidity Scores between the 2 groups (Table 1). The most common comorbidities were hypertension, arrhythmias, and type 2 diabetes mellitus. The majority of patients in both groups were overweight (defined as body mass index 25–29.9) and male.

VADs

16 of 43 patients had their VAD as DT (Table 1). The most common VAD was the Heartmate II in both groups. The majority of patients were supported by a left ventricular assist device (LVAD) (88%). The remainder had a biventricular assist device (BiVAD) (10%) or a total artificial heart (2%).

Coagulopathy and Blood Loss

The median activated partial thromboplastin time and platelet values were normal in the 2 groups (Table 2). Median INR was slightly elevated in both groups (elective INR 1.4, emergent INR 1.6) but neither significantly different ($P = 0.27$) nor in the therapeutic range. Median intraoperative estimated blood loss (EBL) was 2-fold higher in the emergent group (100 mL) than the elective group (50 mL, $P = 0.06$) (Table 3). In the emergent group, EBL ranged from 5 to 4500 mL, with highest blood loss observed in patients undergoing splenectomy; in the elective group, it ranged from 5 to 1300 mL. The probability of having a postoperative bleeding that required transfusion (13% vs 8%) was not significantly different between the elective and emergent groups (Table 4).

Management of Anticoagulation

The approach to perioperative anticoagulation was variable within both groups, with no incidences of device thrombosis. The most commonly used approach was to hold warfarin and start a heparin bridge (43% vs 54%), although a bivalirudin bridge was utilized in 17% of both elective and emergent cases (Table 3). In the elective group, 26% held warfarin for 5 days without a bridge and

TABLE 3. Operative Characteristics

Variable	Elective (n = 21)	Emergent (n = 22)	P
No. of operative cases	23	24	
MAC/local anesthesia	5 (22)	2 (8)	0.24
Laparoscopic	5 (22)	5 (21)	1
Open	13 (57)	17 (71)	0.37
Days to abdominal surgery, median	375 (166.5–758)	265 (110.5–539.5)	0.47
Estimated blood loss, median	50 (12.5–62.5)	100 (50–200)	0.06
Type of operation			
Exploratory laparotomy only	0 (0)	3 (13)	0.23
Hernia repair	6 (26)	2 (8)	0.14
Hepatobiliary operation	5 (22)	3 (13)	0.46
Intestinal operation	6 (26)	10 (42)	0.36
Wound closure/ debridement	0 (0)	1 (4)	1
Other general surgical	4 (17)	3 (13)	0.7
Urologic procedure	2 (9)	2 (8)	1

Data are reported as number (% of cases) or median (interquartile range).
MAC indicates monitored anesthesia care.

TABLE 4. Postoperative Complications

Variable	Elective (n = 21)	Emergent (n = 22)	*P*
No. of surgical cases	23	24	
Length of stay in days, median	8.5 (5–22.5)	12 (3.75–42.5)	0.32
Postoperative complications			
Bleeding requiring transfusion	3 (13)	2 (8)	0.67
Venous thromboembolism (DVT/PE)	0 (0)	3 (13)	0.23
Cerebrovascular accident			
Ischemic	1 (4)	1 (4)	1
Hemorrhagic	0 (0)	1 (4)	1
Superficial surgical site infection	1 (4)	0 (0)	1
Deep surgical site infection	0 (0)	3 (13)	0.23
Device thrombosis	0 (0)	0 (0)	1
Reoperation within 30 days	2 (9)	1 (4)	0.61
24-h mortality rate	0 (0)	2 (8)	0.49
30-day mortality rate	1 (4)	4 (17)	0.19

Data are reported as number (% of cases) or median (interquartile range).
DVT indicates deep vein thrombosis; PE, pulmonary embolism.

resumed it postoperatively. In the emergent group, 29% of patients had warfarin held emergently and resumed it without a bridge postoperatively. Of these, 5 cases (21%) required reversal of anticoagulation with fresh frozen plasma. There were no incidences of device thrombosis in the study.

Postoperative Outcomes

Emergent cases trended toward elevated risk of postoperative morbidity and mortality. Median length of stay was 12 days in the emergent group and 8.5 days in the elective group (Table 4). The emergent group had 13% deep surgical site infection rate and 13% of venous thromboembolic events. The elective group had 4% rate of superficial surgical site infections and no incidence of deep site infections or venous thromboembolic events. Both elective and emergent groups had 4% incidence of embolic stroke. Mortality in the emergent group at 30 days was 17% and 4% in the elective group.

Laparoscopic Approach

Elective laparoscopic cases possessed outcomes analogous to the mixed-cohort as a whole. Five elective cases (hernia repairs, cholecystectomies, liver biopsy) and 5 emergent cases (appendectomies, cholecystectomies) were performed laparoscopically (Table 3). In both groups, median intraoperative blood loss was 50 mL. Median postoperative length of stay in the elective group was 5.5 days, and the emergent group was 9 days. Complications were limited to 1 superficial surgical site infection among the 5 elective laparoscopic cases, with more complications (2 with bleeding, 1 deep surgical site infection, 1 embolic stroke) and 1 death in the emergent laparoscopic group.

Emergent Cases in the Setting of VAD Placement

Emergent cases performed shortly after the time of device placement in the setting of cardiogenic shock had high mortality. Sixty-eight percent (11/16 patients) had postoperative bleeding with subsequent transfusion. 24-hour mortality was high at 44% (7/16 patients), and 30-day mortality was 75% (12/16 patients) in this group.

DISCUSSION

As the technology behind mechanical support of heart failure improves and life expectancy lengthens, the demand for elective and emergent abdominal operations in this population will continue to rise. It is therefore critical for surgeons to understand the risk profile and perioperative management of this patient population. Our study serves as a comprehensive analysis of the outcomes of abdominal surgery in patients with ventricular support devices across major academic institutions. It is the largest study to date on the outcomes of elective operations, as previous studies have smaller sample sizes of n <10.[7,8]

Balancing the risk of bleeding and thrombosis in patients requiring perioperative systemic anticoagulation for ventricular assist devices is a challenge. Reassuringly, the median intraoperative estimated blood loss was small at a median of 50 or 100 mL for elective and emergent cases, respectively, but the range was wide. The risk of postoperative bleeding requiring transfusion was lower than the bleeding rates of 36% to 44% reported in other studies of all noncardiac surgeries in VAD patients.[9,10] In those studies, clinically significant bleeding requiring transfusion had been seen in patients who had continued aspirin/warfarin preoperatively or had INRs >1.9.[10] The patients in our study had lower preoperative INRs. As for embolic and thrombotic disease, there was a low (4%) risk of ischemic stroke in both groups of patients, no device thromboses, and no DVT/PE in the elective group. This is comparable to the 4% risk of DVT/PE reported in the literature for all noncardiac surgery in patients with VAD.[9] The higher (11%) risk of DVT/PE in the emergent group might be attributable to a proinflammatory state caused by the underlying pathology and the need for active reversal of anticoagulation.

Our study corroborates a previous finding in a much smaller sample that VAD patients have an acceptable risk profile for elective surgery.[7] No deaths occurred in the 24-hour postoperative setting, with 1 death in the 30-day posoperative period related to a postextubation aspiration event in a ''Do Not Resuscitate'' patient with peritoneal cancer. Risk of surgical site infection (4% superficial, 0% deep) was low compared to previous studies (9%).[9] In addition, we found a 17% 30-day mortality risk in the emergent group, which is lower than the 23% reported in a query of all noncardiac surgery performed in VAD patients.[9] The substantially higher mortality rates in the 16 patients who underwent emergent abdominal operation after emergent VAD placement in the setting of shock is likely more reflective of their critical illness than the operation itself. The clinicians making decisions to perform abdominal operation in the setting of a cardiogenic shock should take into consideration extremely high mortality and bleeding risk in this subset of patients.

Furthermore, although our study was not specifically powered to examine laparoscopic *versus* open surgery in patients with VADs, the outcomes of our 10 laparoscopic cases did not demonstrate significantly increased 30-day morbidity or mortality compared to the cohort overall. Therefore, although some have questioned the safety of the hemodynamic effects of pneumoperitoneum on VAD patients,[11] our study is consistent with previous findings in similarly small studies[12–13] that laparoscopic procedures appear to be safe in this patient population.

Finally, this is one of the first studies[12] to include outcomes in patients with BiVAD and total artificial heart, which, although currently less commonly used than LVAD, may be increasingly used in the future. Outcomes in this subgroup were not significantly different than LVAD patients, although they made up a small percentage of the total population studied.

Limitations of this study include small sample size and the retrospective nature of the study. The sample size of 57 patients is modest but clinically relevant, having been accrued during a 13-year period from 3 of the largest academic hospitals in Boston. Selection bias plays a role as well, given that there is possibility that surgeons may have chosen to operate on healthier patient with better risk profiles. Owing to some interinstitutional variability in data

recording and the retrospective nature of the study, there were missing data on antiplatelet management, which we could not report on. It would have been beneficial to also provide the information on quality of life postoperatively; however, given the retrospective study design, we could not ascertain this data.

Understanding the surgical risks, preoperative management, and general postoperative prognosis in patients with VADs is crucial for patient counseling and surgical decision-making. This study contributes to the relatively small amount of data on elective and emergent abdominal surgeries in patients with these devices. It suggests that the risk profile of VAD patients for abdominal surgery is acceptable. Given the extended length of time patients are living with cardiac assist devices, with 39% of our cohort having VADs as DT, we must be objective in our assessment of these patients for surgery so as not to deny them therapy that is indicated given their expected quantity and quality of life. Larger, prospective multi-institutional studies are needed to further elucidate risk factors that affect surgical outcomes and provide more standardized guidelines on anticoagulation management to provide better care and counseling for our patients.

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