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Non-cardiac surgery in patients on long-term left ventricular assist device support

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BACKGROUND: An increasing number of patients on left ventricular assist device (LVAD) support are requiring non-cardiac surgical (NCS) procedures. We reviewed our experience with the management of patients on continuous flow (CF) LVAD support undergoing NCS.

METHODS: From March 2006 through March 2011, 86 patients with chronic heart failure underwent implantation of a HeartMate II (Thoratec Corp, Pleasanton, CA) LVAD. Clinical records of these patients were reviewed to identify patients who underwent NCS while on LVAD support, with a focus on peri-operative death, bleeding, thrombosis, and device malfunction, as well as management of pre-operative anti-coagulation.

RESULTS: While on CF-LVAD support, 20 patients underwent 25 NCSs, comprising 13 major and 12 minor procedures. Operations were performed electively in 22 and as emergencies in 3. No peri-operative deaths, thromboembolic complications, or device malfunctions occurred. The incidence of bleeding requiring transfusion of packed red blood cells was 36.0%, including 25% of patients undergoing minor NCSs and 46.2% undergoing major NCSs ($p = 0.004$). All bleeding complications occurred in patients on both warfarin and aspirin pre-operatively. The only significant differences between patients who did and did not require transfusion were pre-operative warfarin use and significantly higher pre-operative international normalized ratio in the transfused group (1.9 ± 0.4 vs 1.4 ± 0.3; $p = 0.008$).

CONCLUSIONS: Non-cardiac operations can be performed safely in patients with CF-LVADs. It may possible to reduce peri-operative bleeding by lowering pre-operative anti-coagulation goals, especially before major surgery. However, additional analysis is required to determine if this can be performed safely.

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Left ventricular assist devices (LVADs) have become an accepted therapeutic strategy for bridge to transplant (BTT) and destination therapy (DT) in patients with refractory end-stage heart failure.[1–3] Miller et al[1] demonstrated 75% survival at 6 months of LVAD support along with a significant improvement in New York Heart Association functional class status in 133 BTT patients awaiting heart transplantation.[1] In the HeartMate II (Thoratec Corp, Pleasanton, CA) pivotal BTT trial, Pagani et al[2] reported that 79% of 281 patients successfully met the primary end point of receiving a transplant, explanted for cardiac recovery, or on ongoing support at 18 months.

As duration of LVAD support has increased, more of these patients require elective non-cardiac surgery (NCS).[3–10] These patients present numerous challenges to non-cardiac care-takers, including anesthesiologists and operating room nurses, who are not familiar with the management of patients who are receiving continuous flow (CF) LVAD support.[11,12]

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In addition, standard CF-LVAD management includes long-term anti-coagulation with warfarin and aspirin. Anti-coagulation management at the time of NCS procedures must balance concerns for device thrombosis and thromboembolism with the potential for bleeding.[13–17] There is minimal published experience relating to these issues. In this study, we review our experience with patients who underwent elective NCS at our institution while on long-term CF-LVAD support.

Methods

From March 2006 through March 2011, 86 patients with chronic heart failure underwent implantation of a HeartMate II (HM II) CF-LVAD at our institution as BTT ($n = 54$) or DT ($n = 32$). The clinical records of these patients were retrospectively reviewed to identify 20 patients who underwent 25 NCS procedures while on LVAD support, with a specific focus on their survival and incidence of LVAD-related complications, including bleeding, device thrombosis, stroke, or device malfunction. The procedures followed were in accordance with institutional guidelines, and this review was performed with Investigational Review Board approval.

The types of NCS procedures performed were recorded, as was the duration on LVAD support at the time of the procedure. Clinical demographic variables recorded included age, sex, race, etiology of heart failure, presence of diabetes, and chronic renal insufficiency. The anti-coagulation regimen at the time of NCS was reviewed, including aspirin, warfarin, and/or intravenous unfractionated heparin use. Platelet count and international normalized ratio (INR) were documented. Patients with HM II CF-LVADs at our institution are routinely anti-coagulated with aspirin and warfarin, with a target INR of 1.8 to 2.5. Bleeding was defined as a post-operative decrease in hematocrit necessitating transfusion of packed red blood cells (PRBCs) or surgical re-exploration.

Data are presented as frequency distributions and percentages. Values of continuous variables are expressed as a mean ± standard deviation. Continuous variables were compared using independent samples *t*-tests, whereas chi-square tests were used to compare categoric variables. For all analyses, a value of $p < 0.05$ was considered statistically significant. Kaplan-Meier analysis was used to calculate survival, along with a log-rank *p*-value when groups were compared. Actuarial survival at 1, 3, and 5 years after implant were calculated by constructing life tables. All data were analyzed using SPSS 11.5 software (SPSS Inc, Chicago, IL).

Results

Demographics

NCS procedures were required in 13 men (65.0%) and 7 women (35.0%) with LVADs. Patients were a mean age 50.1 ± 12.7 years. The etiology of heart failure was coronary artery disease (ischemic cardiomyopathy) in 6 (30.0%) and nonischemic dilated cardiomyopathy in 14 (70.0%). Devices were implanted as BTT in 12 patients and as DT in 8.

Types of NCS procedures

There were 25 NCS procedures performed in 20 patients (Table 1). The procedures performed with the highest frequency included inguinal hernia repair (IHR) in 4, cholecystectomy in 4, bilateral salpingo-oophorectomy (BSO) in 3, release of small bowel obstruction (SBO) in 2, colon resection in 2, lipoma excision in 2, and insertion of a tunneled catheter in 2. General surgical and gynecologic procedures were performed by an open, non-laparoscopic approach. Procedures were performed at an overall median duration of LVAD support of 285 days.

Major vs minor operations

NCS procedures were separated into major and minor cases. There were 13 major cases, which included 4 cholecystectomies, 3 BSOs, 2 SBOs, 2 colon resections, 1 ileofemoral bypass, and 1 gastric bypass. There were 12 minor cases, which included 4 IHRs, 2 lipoma excisions, 2 catheter insertions, 1 endometrial ablation, 1 incision and drainage of a knee abscess, 1 dental extraction, and 1 removal of a tunneled catheter.

Elective vs emergency operations

Operations were performed for elective indications in 22 cases and as emergencies in 3. The emergency operations were two laparotomies for SBO and an incision and drainage of a knee abscess.

Pre-operative management of anti-coagulation

There was substantial variability in the pre-operative anti-coagulation protocols for patients undergoing NCS. For 6 procedures, warfarin was discontinued 5 or more days pre-operatively, whereas aspirin was continued. Intravenous unfractionated heparin was used to bridge 4 of these patients. Aspirin and warfarin were both stopped at least 5 days pre-operatively for 4 procedures, and all 4 of these patients were bridged with intravenous heparin. Finally, aspirin and warfarin were both continued pre-operatively in 15 procedures. The mean INR at the time of NCS was 1.9 ± 0.5 for patients on warfarin and 1.2 ± 0.4 for patients off warfarin for 5 or more days.

Anesthesia and intra-operative monitoring

Anesthesia was administered by general, non-cardiac anesthesiologists, and the operations were performed in the general surgery operating rooms. Induction agents included sevoflurane, isoflurane, and desflurane, along with propofol or etomidate. General anesthesia agents included midazolam, fentanyl, succinylcholine, and cisatracurium.

All patients were accompanied into the operating room by an LVAD coordinator who assisted with the management of the LVAD, including the console, controller, mon-