

Spine Surgery in Patients with Left Ventricular Assist Device

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Abstract

Objective: Left Ventricular Assist Device (LVAD) is a useful tool in terminal heart failure, mainly as destination therapy or as bridge to transplantation. The aim of this study is to describe risk factors and the perioperative management in LVAD patients who need spine surgery procedures.

Patients and methods: This is a retrospective single center study. Electronic files were reviewed from patients who had to undergo LVAD system implantation from January 2011 to December 2020. Risk factors, perioperative management and complications were examined in patients who needed spine surgery procedures.

Result: From Jan 2011 to Dec 2020 in total 626 patients received LVAD systems. 5 Patients (0,8%) had to undergo spine surgery procedures: fracture stabilization n=2; stabilization and debridement in spondylodiscitis n=3. One patient needed revision surgery due to implant failure. A bleeding complication required revision surgery in another case. The mean time from LVAD implantation to spine surgery was 223,5 days (min: 112, max 3675 days). Anticoagulation was present in all patients. No perioperative thrombotic complication was noted. Red blood cell -, fresh frozen plasma- and platelet transfusions were administered in all cases. Perioperative blood pressure dysregulation was mostly seen during the beginning of the anaesthesia and during prone positioning. No patient died.

Conclusion: Spine surgery in LVAD patients is feasible in a multidisciplinary setting without increased mortality. Perioperative coagulation management is crucial to minimize bleeding problems. Thrombotic complications and LVAD system problems do not seem to occur.

Introduction

Heart failure is a complex clinical syndrome which affects around 26 million people worldwide with a significantly increased prevalence among patients >64 years [1-4]. Demographic changes, the advancement in treatments and diagnostic technologies explain the increase in prevalence of heart failure, whereas the incidence is stable or slightly reduced [5,6]. A systematic review and meta-analysis including over 1.5 million heart failure patients estimated the 1, 2, 5 and 10-year survival to be 87%, 73%, 57% and 35%,

respectively [7]. Despite significant advances in therapies and prevention, mortality and morbidity are still high, and the quality of life is poor without adequate treatment. Cardiac transplantation is the only causal therapy in the terminal phase of heart failure, but this therapy is limited due to the restricted donor availability and the required matching and compatibility [8]. Patients often wait for several months to years; 20% die on the waiting list each year without mechanical circulatory support. In these cases, assist

devices are used to improve patient's survival – Ventricular Assist Device (VAD). The Left Ventricular Assist Device (LVAD) is the most common implanted support system (97%, mostly continuous-flow), which demonstrates improved 1- and 2-year survival rates compared to optimal medical therapy [9]. LVAD can be used as bridge to transplant (patients awaiting a heart transplant) or as destination therapy (no candidate for heart transplant) or bridge to recovery (e.g., severe myocarditis), [10]. Since LVAD system provide complete support of the cardiac function with improved patient's comfort and quality of life (discharge at home, ability to exercise), the number of implantations increased continuously [11]. As the number of LVAD grows, risks and complications in the long term follow up are recognized and noncardiac surgical procedures are necessary in some patients. The aim of this study is to evaluate risk factors and perioperative complications in LVAD patients who had to undergo spine surgery.

Patients and Methods

The authors retrospectively reviewed electronic medical records of patients, who underwent LVAD implantation from January 2011 to December 2020 and needed a spine surgery procedure. Patient related demographic parameters, indication for LVAD implantation, indication for spine surgery, preoperative

anticoagulation, perioperative risk factors (evaluated by ASA classification), perioperative management and perioperative outcome (revision surgery) were analyzed.

Inclusion criterion

LVAD Patients that required NCS and general anesthetic from Jan 2011-Dec 2020.

Exclusion criteria

Endoscopic interventions, Surgery due to driveline-infection, ICD Implantation, Patients < 18years

The local ethic committee approved the collection of the data.

Anticoagulation protocol

All patients received long-term anticoagulation with vitamin K dependent anticoagulants in combination with platelet inhibitors (according to international normalized ratio (INR) of prothrombin time 2-3 times the normal value): Heartmate3®: INR 2-2,5; HVAD®: INR 2,5-3. Preoperatively the anticoagulation therapy was bridged to continuous intravenous heparin therapy (target pTT 60-80 sec) when INR < 2. The heparin therapy was stopped 4 hours prior to surgery and continued 6 hours postoperatively [12]. Bridging to peroral anticoagulation was performed postoperatively after secure wound healing.

Result

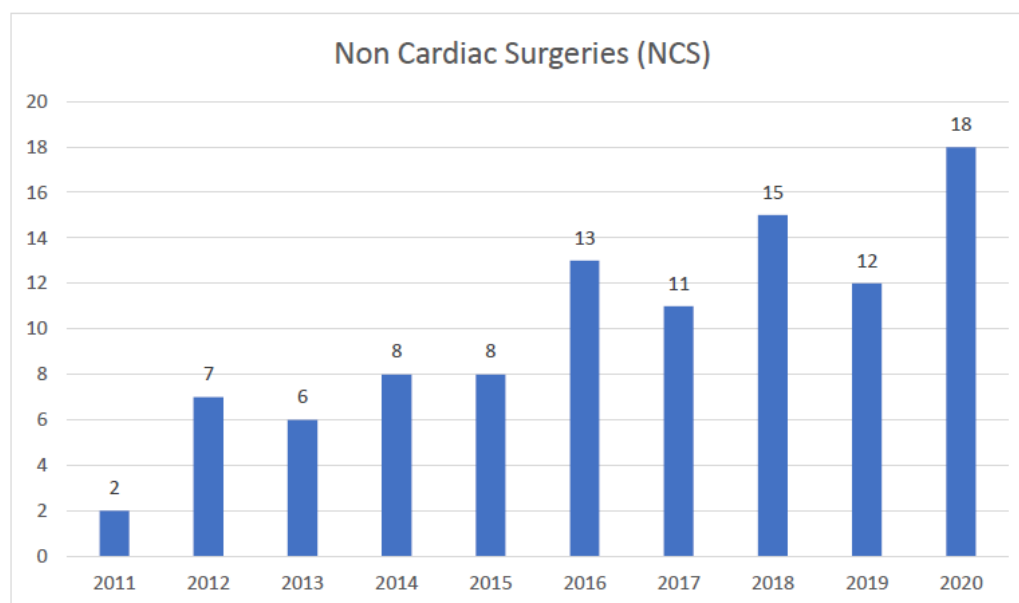


Figure 1: Number of NCS in LVAD patients per year (n=100)

A total of 626 LVAD implantations were performed from January 2011 to December 2020 in our institution. 83 LVAD patients (13,26 %) underwent general anesthesia for 100 noncardiac surgical procedures: Abdominal surgery: 58%; Orthopedic surgery: 29%; Others (endovascular procedures, soft tissue procedures): 13%; Revision surgery due to bleeding: 11%. Fig. 1 demonstrates the

increasing number of NCS from 2011 to 2020 [Figure 1].

Patients with Spine Surgery

5 male LVAD patients (median 65 years, min 52 years, max 69 years) had to undergo 8 spine surgery procedures (8% of all NCS). 2 of the 5 patients received the LVAD system as bridge to transplant

and 3 patients as destination therapy. The mean time from LVAD implantation to spine surgery was 223,5 days (min 112, max 3675). 8 spine procedures were performed in 5 patients: 4 surgeries were performed in prone position, 3 surgeries in the right lateral decubitus and 1 cervical spine surgery in supine position. Revision

surgery was necessary in 1 patient with bleeding complication and hemothorax after thoracic vertebral body replacement. The mean duration of hospital stay was 92,3 days (min 26, max 164). Tab 1. demonstrates the patient related demographics and parameters [Table 1].

Table 1: LAVD patients with spine surgery (n=5).

Patient	Sex	Age	ASA	Indication for LVAD	LVAD System	LVAD target	Indication for surgery	Surgical Procedure	Time to Spine Surgery (d)	Anticoagulation	Periop Anticoagulation
1	M	65	3	DCM	Heart-mate III	DT	L2 and L3 fracture	Percutaneous posterior fracture stabilization	112	Sodium warfarin	Continuous intravenous heparin therapy (target pTT 60-80 sec)
2	M	69	3	ICM	Heart-mate III	DT	T12 fracture	Staged percutaneous posterior and mini-open anterior stabilization	204	Sodium warfarin	Continuous intravenous heparin therapy (target pTT 60-80 sec)
3	M	52	4	DCM	Heart-mate III	BTT	Spondylodiscitis L1/2, L2/3	Open debridement and posterior stabilization	638	Sodium warfarin	Continuous intravenous heparin therapy (target pTT 60-80 sec)
4	M	69	4	DCM	Heart-ware	DT	Spondylodiscitis L4/5	Staged percutaneous posterior and mini-open anterior debridement and stabilization	559	Sodium warfarin	Continuous intravenous heparin therapy (target pTT 60-80 sec)
5	M	65	4	DCM	Heart-ware	BTT	Spondylodiscitis C4/6	Anterior debridement and stabilization	3675	Sodium warfarin	Continuous intravenous heparin therapy (target pTT 60-80 sec)

DCM: dilated cardiomyopathy; ICM: ischemic cardiomyopathy; DT: destination therapy; BTT: bridge to transplant.

Perioperative management

Monitoring

All the patients were monitored with arterial and central venous lines. A transesophageal echocardiogram was performed in 3 cases intraoperatively. LVAD monitoring ran continuously in all cases (flow, pulse index, speed and power) under supervision of a specialist.

Perioperative adverse events / complications

We did not recognize any right ventricular failure, no thromboembolic event, no pump dysfunction.

LVAD alarm

LVAD alert was registered in 4 cases due to a low-flow situation

(hypovolemia). This problem was solved by LVAD pump speed reduction and kolloid infusion.

Hypotension / hypertension

An intraoperative hypotension (MAP<70/20 min) was observed in 8 of 8 cases. This was mainly during the introduction of anaesthesia (n=3) and prone positioning (n=3). An intraoperative hypertension (MAP>90/20 min) was observed in 5 of 8 cases (introduction of anaesthesia n=3; during the operation n=2, lateral positioning n=1).

X-ray and hardware

In one case of percutaneous screw fixation the surgeon had visualization problems due to the hardware (driveline, pump).

Bleeding/ Thrombosis

No bleeding complication occurred intraoperatively. Postoperative interventions due to continuous bleeding was necessary in two cases: One patient developed epistaxis and hematochezia. This was stopped bei tamponade and endoscopic cauterization in the colon sigmoideum. One patient developed an hemothorax due to bleeding out of an intercostal artery. This was stopped by endovascular embolization. A staged evacuation of the hematoma was necessary. No thrombotic complication has been observed during the perioperative period.

Blood product supply

The administration of red blood cells was necessary in 7 cases (n=55U), of PPSB-concentrate in 3 cases of fresh frozen plasma in 2 cases (n=11U) and of platelet concetrare in 1 case (n=1U) perioperatively.

Discussion

A total of 626 patients received LVAD system from January 2011 to December 2020 as bridging or as destination therapy in an end stage heart failure. 100 non cardiac surgeries were necessary in 83 patients (13,26%). 8 spine surgeries were performed in 5 patients. More than the half of the NCS in our population were abdominal surgeries (58%), orthopedic surgeries occurred in 29%. This is consistent with most studies [13,14]. The mean age in our overall NCS population was 59,4 years ($\pm 10,34$), 88% were male. The comorbidities in our NCS population did not differ from other reported LVAD patients with NCS: Most patients suffer from valvular heart disease, hypertension, coronary arterial disease. We regognized an overall mortality rate of 14,5% in the NCS group. The 30 days mortality after NCS is reported between 0 and 56% [15,8,16]. We observed a continuous increase of NCS from n=2 in 2011 to n=18 in 2020. This is consistent with other publications [14,12]. This is related to the demographic change, an increasing number of implantations, expansion of indication and better understanding in the perioperative management of NCS. The increasing number of LVAD implantation leads to an increasing number of non-cardiac interventions and surgeries. The risk of readmission for NCS in LVAD patients is up to 10 % [17]. LVAD patients undergoing noncardiac procedures most frequently require upper or lower endoscopies (65%) and most of the procedures (95%) were elective or nonemergent procedures. Stone et al. reported of 138 LVAD patients who underwent 291 procedures in a study period of ten years (2003-2013). Upper and lower endoscopies were performed in 35,74% [18]. Degnan et al. reported of an average of 2.4 procedures per patient, 97% survived to discharge after their procedure [14]. A recent study of Berger et al. reported of a total of 105 surgical procedures in 63 LVAD patients. General anesthesia was required in 100 cases (abdominal surgery: 15,24%, neurosurgery: 8,57%, orthopedic surgery: 7,62%). It should be mentioned that they included LVAD related complications like late wound infections and driveline complications (24 cases; 22,86%) and pacemaker / ICD implantation and revisions (24 cases; 22,86%). The authors found a perioperative mortality of 3.8% with in the first 30 days and concluded that non-cardiac surgery can be

performed on LVAD recipients with acceptable mortality [13]. To the best of our knowledge, this is the first study that investigates spine surgery procedures in LVAD patients. The mean time from LVAD implantation to surgery in our population was 223,5 days (min 112, max 3675). Berger et al. reported an interval between LVAD implantation and NCS of 645 days [13], Mathis et al. of 370 days [16] and Chen et al. of 329 days [19]. The median length of hospital stay due to NCS is 14.4 (± 14.6) days and it is significantly higher compared with LVAD recipients admitted for other reasons except for NCS [17]. We recognized a much longer duration of hospital stay with at mean 92,3 days (min 26, max 164) in our spine surgery group. The reason for that is due to the necessity of preop and postop bridging (INR), the kind of surgery (staged anterior and posterior procedures) and revision surgery due to bleeding. In accordance with the literature our LVAD patients undergoing NCS are slightly older and have more cormorbidities compared to non NCS patients [17]. The mean age of LVAD patients undergoing noncardiac surgeries is 58.8 years [17]. Our spine patients were 65 years old and on average 5.6 years older than the most NCS patients. In our population two patients (40%) were classified as grade 3 and three patients (60%) as grade 4 according to the ASA classification. Mathis et al reported ASA 3 in 13,1%, ASA 4 in 85,8% and ASA 5 in 1,1% [16]. Ischemic cardiomyopathy (ICM) is the reason for LVAD implantation in most cases [16,20]. In our population, only one patient suffered from ICM, four patient (80%) demonstrated a dilated cardiomyopathy (DCM) as indication for LVAD. 2 of the 5 patients (40%) received the LVAD system as bridge to transplant and 3 patients (60%) as destination therapy. Other authors reported a more balanced distribution between destination therapy and bridg to transplant therapy [16]. Spine surgery was performed in prone position in 4 cases, in right lateral decubitus in 3 cases and in supine position in one case. Especially the prone position needs attention in LVAD patients: Pulling and kinking of the driveline should be avoid. As X-ray visualization is mandatory in percutaneous spine surgery, the pump and the driveline should be out of the operation field. Further the contact of disinfectants can lead to LVAD pump failure or damage. Hemodynamic alterations during prone positioning can lead to major problems in LVAD patients. When moving a patient into the prone position an average decrease in cardiac index (CI) of 24% occurs (decrease in stroke volume) [21]. Positioning in a convex frame further can cause a decrease in CI and stroke volume index with no significant increase in inferior vena cava (IVC) pressure. The obstruction of the inferior vena cava by abdominal compression leads to decreased cardiac output, increased bleeding, venous stasis and consequent thrombotic complications. Careful positioning with free hanging abdomen is decisive in LVAD patients especially because these patients have reduced compensatory mechanisms [22,21]. Therefore, MAP of <85-90 mmHg is recommended perioperatively [22]. Hypertension during the induction of anaesthesia should be avoided to minimize pump failure [8]. Arterial and central venous lines are recommended for continuous hemodynamic monitoring. An intraoperative TEE should be performed in case of suspected severe volume alteration [24,18]. The international Society for Heart and Lung Transplantation recommends a continuously LVAD

monitoring under supervision of a specialist [25]. We observed hemodynamic alteration outside the proposed MAP target area without instability or pump dysfunction in 8 of 8 cases, mostly during the introduction of anaesthesia and prone positioning. Intraoperative Hypotension is reported by other authors in 27% [16]. MAP > 90 mmHg is associated with a 34% increased risk of perioperative stroke events [26]. Therefore a strictly anticoagulation regime is crucial in LVAD patients to avoid thrombotic events, especially pump thrombosis. In case of major noncardiac surgical procedures perioperative bridging is necessary to avoid bleeding problems. In non-emergency surgeries the switch of the long-term warfarin therapy to an intravenous heparin therapy with target partial thromboplastin time between 60 and 80 seconds is recommended [8]. In our population the mean INR was 1,5 and the mean PTT 44,5 sec 4 hours prior surgery. This corresponds to the general recommendations and reports of other authors [16,27]. Bleeding is one of the major complications in LVAD patients with NCS [19,12]. Abnormal bleeding occurs in almost 50% of patients. The yearly risk for developing a GI bleed is almost 9% [28].

The bleeding risk is based on various factors:

1. An acquired von Willebrand deficiency due to shear forces and enzymatic degradation of the factor by the pump [29-31].
2. The development of gastrointestinal arteriovenous malformations [32].
3. The necessity of longterm anticoagulation with warfarin (INR: 2 - 2.5) [33].

We recognized a lower GI bleed in one case, which was controlled by endoscopic cauterization. Other authors demonstrated clinical benefits of octreotide in the treatment of LVAD-associated GI bleeds [34,35]. In one case we had to deal with an intercostal artery bleed, which was stopped by selective embolization. Regarding the literature NCS is associated with the transfusion of perioperative blood products in 62% [14,28,36]. Therefore, a sufficient blood product allocation is recommended preoperatively. In our small group of 5 patients and 8 spine procedures the administration of red blood cells was necessary in 7 cases (n=55U) perioperatively. The application of cell saver systems is recommended in case of extended bleeding and procedures with high bleeding risk. 3 LVAD patients in our study needed surgery due to spinal infection and proven bacteremia, which represents a contraindication for the use of cell savers. One patient underwent percutaneous stabilization due to a pathologic fracture. Tumor condition represents a contraindication as well. Antidote or blood supplements are recommended in anticoagulated patients who need emergency surgery to avoid bleed and circulation problems. But the risk of LVAD pump thrombosis and pump failure must be considered [13]. Our patients received PPSB-concentrate in 3 cases, fresh frozen plasma in 2 cases (n=11U) and platelet concentrate in 1 case (n=1U) perioperatively. We did not recognize thrombotic events or pump failure. In one case of transthoracic vertebral body replacement, we had access difficulties due to an extensive scarring after LVAD implantation. These problems might be reduced in the future by optimizing device design and minimally invasive LVAD

implantation [37].

Limitation

Due to the retrospective nature of our study, data were limited to that which was recorded for clinical care purposes. LVAD patients who were admitted to external institutions for NCS might be missing. The number of spine procedures in this NCS group is very small, major complication and adverse events might be undetected.

Conclusion

To the best of our knowledge this is the first report of spine surgery procedures in LVAD patients. We did not find considerably differences in morbidity and complication rates compared to other reported NCS. The risk of perioperative bleeding is known and should be controlled by strictly bridging management and blood product supplementation. Prone positioning might be a problem for hemodynamics, that's why continuously monitoring is mandatory. No patient died perioperatively. As LVAD implantation will increase, the number of NCS and also spine surgeries will increase in the future. Spine procedures are feasible in LVAD patients. We recommend surgery in LVAD patients in specialised centers to reduce morbidity rates in these complex patients.

Acknowledgment

None.

Conflict of interest

No conflict of interest.

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