A difficult decision: what should we do when malignant tumours are diagnosed in patients supported by left ventricular assist devices?

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Abstract

OBJECTIVES: Left ventricular assist devices (LVADs) are used as a bridge to heart transplantation. During the preimplantation or pretransplantation screening, malignant tumours can be discovered. Owing to the lack of guidelines, the management is difficult. We describe our perioperative approach and the patients’ outcomes.

METHODS: Between 2006 and 2014, 55 patients underwent implantation of HeartMate II LVAD. Five were diagnosed with malignant tumours: 2 renal, 2 lung and 1 breast tumours. The renal tumours were diagnosed during the preimplantation screening. An LVAD was implanted in both followed by partial nephrectomies 8 and 9 months later. The lung cancers were diagnosed after device implantation, a left pulmonary segmentectomy and a right upper sleeve lobectomy were performed. The breast cancer was diagnosed few months after support and a tumourectomy with lymphadenectomy was performed.

RESULTS: Tumour resection was performed successfully in all patients. Prior to surgery haemostasis, device and heart function were evaluated. During surgery, haemodynamics and anticoagulation were monitored. Reoperations were necessary to evacuate haemothorax after lobectomy and an abdominal haematoma post-nephrectomy. After discussion with oncologists, 3 patients were relisted for heart transplantation. Two were successfully transplanted 2 and 3 years after partial nephrectomy with an actual survival of 56 and 59 months after the cancer diagnosis. The follow-up revealed no cancer recurrences.

CONCLUSIONS: Malignant tumours during support with LVAD can be successfully resected. A multidisciplinary evaluation in these high-risk patients is mandatory. After careful evaluation, regaining the patient’s heart transplant candidacy is possible.

Keywords: Malignant tumours • Left ventricular assist device • Transplantation • Extracardiac surgery

INTRODUCTION

Left ventricular assist device (LVAD) has become an important option in the treatment of end-stage heart failure and more than 20,000 patients worldwide have now been implanted with a continuous flow LVAD [HeartMate II (HMII), Thoratec Corporation, Pleasanton, CA, USA] and over 6000 patients are on ongoing support (Thoratec data).

HMII devices are increasingly used as a bridge to heart transplantation and the expanded application of LVAD therapy over the past decade [1] has led to a significant improvement in waiting-list mortality.

During the pretransplantation screening, malignant tumours can be diagnosed in patients supported with HMII, in patients suffering an acute heart failure and under extracorporeal membrane (ECMO) support or in patients with chronic heart failure before LVAD implantation.

Those particular transplant candidates suffer potentially reversible transplant contraindications. If discovered, these malignant tumours will pose a unique challenge to clinicians because as to date there have been no management guidelines [2]. When cancer resection is indicated, it will pose another challenge to surgeons, according to two distinct cases: the first case concerns patients not yet supported with LVAD and under ECMO support, in which the invasive surgical approach for cancer resection may often be difficult in relation to deteriorating heart failure; the second case concerns the patients already supported with LVAD who need extracardiac surgery to resect the tumour.
The number of patients supported with LVAD undergoing extra-cardiac procedures for cancer is expected to increase [3, 4] as more LVADs are implanted and the pretransplantation contemporary image screening is becoming more effective to detect cancers. Therefore, it will be crucial that cardiologists, surgeons and anaesthetists be knowledgeable in the management of these patients [5].

The objective of this study was to describe the perioperative management of malignant tumours in HMII LV AD patients, regarding the haemodynamic, haemorrhagic and infection risks during the surgery and the outcome considerations regarding the inclusion of the patients on the cardiac transplant waiting list.

METHODS

Patient characteristics

From 2006 to 2014, 55 patients were implanted with a continuous flow LVAD (HeartMate II, Thoratec Corporation, Pleasanton, CA, USA) in our institution and five malignant tumours were diagnosed. The 5-patient cases are summarized in Table 1 and presented below:

(i) Case 1: a 30-year old man with dilated cardiomyopathy presented with acute severe heart failure requiring veno arterial ECMO. During the pretransplantation screening, the body computed tomography (CT) scan revealed a mass (3 cm) on the upper pole of the left kidney with a negative metastatic workup. A histological diagnosis with CT-guided biopsy was attempted despite the high risk of bleeding but without success. The suspicion of malignant renal tumour suspended the inclusion of the patient on the cardiac transplant waiting list. A multidisciplinary case conference was held with a panel of transplant cardiologists, anaesthesiologists and urologists. Given to the high surgical risk, we concluded that the patient needed to be supported by a LVAD before the tumour resection. We implanted a non-preclotted version of HMII device and 8 months later, we performed a partial left nephrectomy. The histological diagnosis confirmed an adenocarcinoma grade II of Fuhrman.

(ii) Case 2: a 51-year old man with NYHA class IV dilated heart failure was diagnosed during the pretransplantation screening with a localized renal tumour (2.6 cm) on the inferior pole with a negative metastatic workup. After this diagnosis, we decided to delist the patient pending treatment of the tumour. Owing to the patient’s deteriorating heart failure, invasive surgery was contraindicated. Therefore, a non-preclotted version of HMII device was implanted and the partial left nephrectomy was performed 9 months later. The histological diagnosis confirmed the tumour as a low-grade adenocarcinoma grade I of Fuhrman.

(iii) Case 3: a 60-year old man, with a history of renal cancer 5 years ago with complete remission, presented 2 years earlier with ischaemic heart failure and was implanted with a non-preclotted version of HMII LVAD. Patient pretransplantation screening revealed an isolated left pulmonary nodule with negative metastatic workup. After this diagnosis, the patient was considered not eligible for heart transplantation and we performed a left segmentectomy under videothoracoscop for the resection of the suspicious pulmonary nodule. Histology revealed a diagnosis of renal metastasis.

(iv) Case 4: a 48-year old woman, with a history of left breast cancer 8 years ago with total remission and dilated cardiomyopathy, presented with severe heart failure that necessitated emergent VA-ECMO and a preclotted version of HMII LVAD support. The patient was likely to be listed for heart transplantation. We diagnosed a left breast tumour without metastasis during the pretransplantation screening. Nine months later, we performed resection of the breast tumour and an axillary lymphadenectomy. Histology revealed an in situ ductal carcinoma.

(v) Case 5: a 61-year old man with ischaemic cardiomyopathy presented with severe heart failure that necessitated emergent VA-ECMO and a preclotted version of HMII LVAD support. The patient was likely to be listed for heart transplantation. One year after HMII implantation, he presented haemoptysis and the CT scan diagnosed a suspicious right upper pulmonary tumour. The metastasis workup was negative. We performed a right upper sleeve lobectomy under thoracotomy. Histology revealed a well-differentiated epidermoid carcinoma.

Preoperative care

Anticoagulation and haemostasis assessment. The routine anticoagulation regimen used in our centre is vitamin K antagonists (fluindione) without any antiplatelet therapy with target international normalized ratio (INR) of 2–2.5. The monotherapy anticoagulation

<table>
<thead>
<tr>
<th>Case</th>
<th>Status during cancer diagnosis</th>
<th>Type of cancer</th>
<th>Date of cancer diagnosis</th>
<th>Date of VAD implantation</th>
<th>HMII: version</th>
<th>Date of cancer resection</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>ECMO support</td>
<td>Renal adenocarcinoma</td>
<td>4 September 2010</td>
<td>28 September 2010</td>
<td>Non-preclotted</td>
<td>11 May 2011</td>
</tr>
<tr>
<td>2</td>
<td>Chronic heart failure</td>
<td>Renal adenocarcinoma</td>
<td>1 January 2010</td>
<td>04 March 2010</td>
<td>Non-preclotted</td>
<td>24 November 2010</td>
</tr>
<tr>
<td>3</td>
<td>VAD support</td>
<td>Pulmonary metastasis</td>
<td>27 November 2009</td>
<td>29 April 2009</td>
<td>Non-preclotted</td>
<td>11 June 2010</td>
</tr>
<tr>
<td>4</td>
<td>VAD support</td>
<td>Breast ductal carcinoma</td>
<td>22 November 2012</td>
<td>8 March 2012</td>
<td>Preclotted</td>
<td>11 January 2013</td>
</tr>
<tr>
<td>5</td>
<td>VAD support</td>
<td>Pulmonary epidermoid carcinoma</td>
<td>13 March 2013</td>
<td>21 February 2012</td>
<td>Preclotted</td>
<td>18 September 2013</td>
</tr>
</tbody>
</table>

ECMO: extracorporeal membrane oxygenation; VAD: ventricular assist device; HMII: HeartMate II.
strategy has been used since the beginning of HMII device implantation in our centre [6]. Patients supported with HMII devices have a high risk of surgical bleeding due to their required anticoagulation. The 5 patients were maintained on vitamin K antagonists. Five days prior to surgery, we hospitalized them in order to substitute the vitamin K antagonist with heparin. The strategy of regular anticoagulation and the altered protocol before surgery is highlighted in Fig. 1. The mean values of INR and partial thromboplastin time (PTT) 1 month and 1 day before surgery are summarized in Table 2.

We performed exhaustive haemostasis testing including testing for acquired von Willebrand disease (AvtWD). A diminished ratio of collagen-binding capacity and ristocetin cofactor activity to von Willebrand factor (vWF: RCo/vWF: Ag < 0.65) was observed in 3 of the 5 patients with breast, renal tumours and lung cancer. These patients did not receive any vWF concentrate (Wilfactin; LFB, Les Ulis, France) before surgery.

**Echocardiography assessment.** Before surgery, the cardiologists assessed the device and the right ventricle function. A transthoracic echocardiography was used in all patients and neither pump dysfunction nor right ventricular failure was diagnosed.

**Prophylactic antibiotics.** The prevention of infection is crucial in these LVAD patients. The anaesthetists prescribed a combination of wide-spectrum antibiotics including vancomycin, rifampicin and fluconazole before surgery and for 48 h after surgery. Two of the 5 patients had an HMII driveline infection caused by Staphylococcus aureus. In these patients, specific antibiotics prescribed for the ongoing infection were added to the antibiotic prophylaxis.

**RESULTS**

**Operative care**

All the procedures were performed in the cardiac surgery operative room with the presence of a cardiac surgeon. The surgical procedures were achieved under general anaesthesia with rapid sequence induction as these patients are considered full stomach because of the stomach compression by the HMII pump. Patients undergoing pulmonary resection were ventilated with a double lumen endotracheal tube and single lung ventilation was achieved during the procedure without difficulties. An arterial line, venous catheter (central venous pressure) continuously monitored the patient’s haemodynamic status, and the patient was connected to the HMII monitor to be able to adjust the device parameters if needed during the surgery. The patient’s position was carefully changed to the right lateral decubitus during nephrectomies and pulmonary surgery. This resulted in decreased cardiac output, which resolved with the administration of vasopressors and hydration in 2 patients, and with a decrease in the pump speed by 200 RPM in the case of pulmonary videothoracoscopy. To avoid interference between the implantable cardiac defibrillator and the electrocautery, we used bipolar electrocautery, turned off the implantable cardiac defibrillator and used external defibrillator pads.

**Table 2:** Anticoagulation management before, during and after cancer resection

<table>
<thead>
<tr>
<th>Case</th>
<th>HMII version</th>
<th>INR 1 month before surgery: VKA (fluindione)</th>
<th>INR, PTT 1 day before surgery: (heparin only)</th>
<th>INR, PTT on the day of surgery: (heparin only)</th>
<th>INR, PTT on the day after surgery: (heparin only)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Non-preclotted</td>
<td>2.37 ± 0.23</td>
<td>1.03 ± 0.01</td>
<td>1.3 ± 0.1</td>
<td>1.06 ± 0.01</td>
</tr>
<tr>
<td>2</td>
<td>Non-preclotted</td>
<td>2.48 ± 0.68</td>
<td>1.20 ± 0.02</td>
<td>1.3 ± 0.1</td>
<td>1.01 ± 0.01</td>
</tr>
<tr>
<td>3</td>
<td>Non-preclotted</td>
<td>2.04 ± 0.63</td>
<td>1.36 ± 0.02</td>
<td>1.24 ± 0.04</td>
<td>1.32 ± 0.01</td>
</tr>
<tr>
<td>4</td>
<td>Preclotted</td>
<td>2.22 ± 0.57</td>
<td>1.40 ± 0.02</td>
<td>1.28 ± 0.04</td>
<td>1.26 ± 0.01</td>
</tr>
<tr>
<td>5</td>
<td>Preclotted</td>
<td>2.25 ± 0.75</td>
<td>1.23 ± 0.04</td>
<td>1.24 ± 0.04</td>
<td>1.45 ± 0.01</td>
</tr>
</tbody>
</table>

INR: international normalized ratio; PTT (s): partial thromboplastin time (s).
**Surgical procedures**

During the left pulmonary segmentectomy under videothoracoscopy, dense adhesions of the left upper lobe to the outflow graft of the HMII were encountered. Dissection was laborious but not highly haemorrhagic (Fig. 2).

Nephron-sparing surgery is superior to radical nephrectomy in preserving renal function outcome in renal tumours [7]; therefore, urologists performed left lobotomies to allow superior and inferior partial left nephrectomy for the resection of renal adenocarcinomas.

To avoid bleeding, local haemostatic agents and tissue sealants were used. At no point, did the LV AD present any technical difficulties.

Gynaecologists performed an uneventful resection of the left breast tumour with axillary lymphadenectomy.

During all of the procedures, heparin was administered intravenously with continuous PTT monitoring with a target of PTT 1.5–2 times control. All the values of INR and PTT during the surgery are summarized in Table 2. One of the patients experienced bleeding during the sleeve pulmonary lobectomy. He presented an AvWD preoperatively, we managed the bleeding with fresh frozen plasma and he did not receive any further vWF concentrate (Wilfactin; LFB, Les Ulis, France).

**Postoperative management**

Postoperative care was performed in the cardiac intensive care unit. Patients who underwent breast tumourectomy and pulmonary segmentectomy were extubated in the operative theatre; the 3 others were extubated at 2, 6 h and 2 days postoperatively.

The values of INR and PTT after surgery are summarized in Table 2. The estimated blood loss during the surgery for the upper nephrectomy, inferior nephrectomy, videothoracoscopy, breast tumour resection and sleeve pulmonary lobectomy was respectively 450, 150, 180, 20, 630 ml in total (Table 3).

The patient haemodynamic status postoperatively was stable and the range of length of stay in intensive care unit was 1–8 days and hospital stay was 12–15 days. No infection of the surgical site was observed. Vitamin K antagonist therapy was reintiated in all of the patients after the drain tube removal.

Reoperation was necessary in 2 patients for bleeding. One patient was reoperated 6 h postoperative to evacuate haemothorax after the sleeve lobectomy. He underwent red cell transfusion (four packed red blood cells) and coagulation factors were administered. Another patient was reoperated on postoperative day 30 to evacuate an abdominal haematoma after the partial nephrectomy. The patient presented with left-sided abdominal pain and an abdominal tomodensitometry showed a large haematoma in the renal lodge, the level of anticoagulation was high (INR: 3.2).

**Therapeutic option and long-term outcomes**

For all of the tumours, adjuvant therapy was not necessary, neither chemotherapy nor radiotherapy. Hormone therapy was prescribed in the breast ductal carcinoma.

Relisting the patients on the transplant list is a challenging decision; therefore, it was discussed with a panel of transplant cardiologists and oncologists.

Owing to the low grade of tumour malignancy and the negative metastatic workup, patients who were operated for renal cancer (Cases 1 and 2) regained candidacy for heart transplantation after 2 and 3 years of complete remission. They received orthotopic heart transplantation. The clinical and radiological follow-up revealed no cancer recurrences or transplant rejection.

The patient (Case 3) with the renal pulmonary metastasis was on DT until he died from material defect after 8 years of HMII support. The patient (Case 4) with breast cancer was relisted after 1 year of complete remission. One year later, she died from an acute pump thrombosis. The remaining patient (Case 5), 2 years after tumour resection, the clinical and radiological follow-up showed no cancer recurrences. He is on the waiting transplant list.

The survival of the patients after the cancer diagnosis is successively of 56, 58, 75, 24 and 22 months (Table 4).

**DISCUSSION**

**Diagnosis of malignant tumours in patient with end-stage heart failure**

Metastatic or advanced cancers are commonly considered as an absolute contraindication to the implantation of a cardiac mechanical support [8]. However, some authors considered malignant tumours as a reversible contraindication to heart transplantation [9]. Until now, there have been no series or standards of care for the management of malignant tumours in LVAD patients.

Recently, a new approach of this problem emerged, leading to the first recommendations from the 2013 meeting of the International Society for Heart and Lung Transplantation (ISHLT) for malignancy in LVAD [2]. These recommendations indicated...
that patients with a history of a treated cancer who are in long-term remission or who are considered free of disease might be candidates for mechanical support as a bridge to transplantation. The involvement of an oncologist is required to determine the risk of recurrence or progression. Patient with a history of recently treated or active cancer, who has a reasonable life expectancy (2 years), may be a candidate for DT.

Although rare, we diagnosed and managed 5 patients with end-stage heart failure and malignant tumours. Regarding the renal tumours, these were discovered before the implantation of the LV AD (One of them was under VA-ECMO). We aimed to have a histological diagnosis with a CT-guided biopsy but the location of the lesions prevented the diagnosis.

After discussion with the urologists, in the absence of certain malignancy and given the young age of the 2 patients, we were eager to perform a surgical partial nephrectomy. Even though the risk of bleeding is higher than in total nephrectomy, authors in multicentre study about partial nephrectomy reported excellent cancer control and outcomes in carefully selected patients presenting with tumours >4 cm, and that nephron-sparing surgery is superior to radical nephrectomy in preserving renal function outcome [7].

Given the young age of the patients, the reasonable life expectancy >2 years and the negative metastatic workup, we first implanted an LVAD and then performed the surgical resection of the lesions 8 and 9 months later. This strategy allowed a complete recovery from the VAD implantation and cardiac rehabilitation.

**Extracardiac surgery in left ventricular assist device patients**

The need to treat surgical problems that arise in LVAD patients is growing as the number of implanted devices and length of support increases. We diagnosed three tumours (three pulmonary and one breast cancer) in patients already implanted with LVAD during the screening for the inclusion on the heart transplantation waiting list. Several series describe the management of non-cardiac surgery in patients supported with LVAD and recommend a strong collaboration between cardiac, non-cardiac surgeons and anaesthesiologists to establish a perioperative strategy [10].

All our patients were operated in the cardiac surgery department with the direct collaboration of the cardiac surgeons. This has been highlighted in ISHLT recommendations: ‘A cardiovascular surgeon should be in the operating room or immediately available especially in situations when the non-cardiac procedure is occurring close to the LVAD’ [2]. The surgery under LVAD support was marked by a high risk of bleeding, infection and haemodynamic failure.

Bleeding is the most frequent surgical complication, occurring in 48% of patients in a series of 27 extracardiac procedures [11] and requiring reoperation in 50% of patients in a series of 20 procedures [12]. In our series, peri- and postoperative bleeding was due to continuous operative anticoagulation and to the von Willebrand disease diagnosed in 3 patients. Two of the 5 (40%) patients required reoperation for bleeding. This risk is higher in cancer patients and in redo thoracic surgeries.

**Table 3: Management of the bleeding during the cancer resection**

<table>
<thead>
<tr>
<th>Case</th>
<th>HMII version</th>
<th>Blood-loss during the procedure</th>
<th>Transfusion during the procedure</th>
<th>Blood loss in the ICU</th>
<th>Transfusion in the ICU</th>
<th>Reoperation for bleeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Non-preclotted</td>
<td>230 ml</td>
<td>No</td>
<td>450 ml</td>
<td>Red blood cells</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>Non-preclotted</td>
<td>100 ml</td>
<td>No</td>
<td>150 ml</td>
<td>No</td>
<td>Yes (Day 30)</td>
</tr>
<tr>
<td>3</td>
<td>Non-preclotted</td>
<td>340 ml</td>
<td>No</td>
<td>180 ml</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>4</td>
<td>Preclotted</td>
<td>20 ml</td>
<td>No</td>
<td>0</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>Preclotted</td>
<td>750 ml</td>
<td>Red blood cells, platelets</td>
<td>630 ml</td>
<td>Red blood cells, FFP</td>
<td>Yes (Day 1)</td>
</tr>
</tbody>
</table>

FFP: fresh frozen plasma; ICU: intensive care unit.

**Table 4: Patient outcomes**

<table>
<thead>
<tr>
<th>Case</th>
<th>Date of cancer diagnosis</th>
<th>Inscription on the waiting list</th>
<th>HTx</th>
<th>Date of HTx</th>
<th>Survival since cancer diagnosis (months)</th>
<th>Outcome in January 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>04 September 2010</td>
<td>01 December 2012</td>
<td>Yes</td>
<td>07 February 2013</td>
<td>56</td>
<td>Alive</td>
</tr>
<tr>
<td>2</td>
<td>02 January 2010</td>
<td>04 May 2013</td>
<td>Yes</td>
<td>24 August 2014</td>
<td>59</td>
<td>Alive</td>
</tr>
<tr>
<td>3</td>
<td>27 November 2009</td>
<td>DT</td>
<td>No</td>
<td>–</td>
<td>75</td>
<td>Death on 27 November 2014</td>
</tr>
<tr>
<td>4</td>
<td>22 November 2012</td>
<td>DT</td>
<td>No</td>
<td>–</td>
<td>24</td>
<td>Death on 23 November 2014</td>
</tr>
<tr>
<td>5</td>
<td>13 March 2013</td>
<td>10 February 2014</td>
<td>No</td>
<td>Waiting list</td>
<td>22</td>
<td>HTx waiting list</td>
</tr>
</tbody>
</table>

HTx: heart transplantation; DT: destination therapy.
Malignant tumours and heart transplantation

Regaining candidacy for heart transplantation after cancer resection in patients supported with HMI is an unusual situation and the decision is difficult. The prevalence of pretransplantation malignancy in patients supported with HMI is unknown; it was described once in the literature, after a robotic-assisted laparoscopic radical prostatectomy for prostate cancer in a 60-year-old man, who successfully received heart transplantation 1 year later [17]. The prevalence of pretransplantation malignancy in heart transplant candidates is 2–3% [18], a history of pre-existing malignancy has been considered as a contraindication to cardiac transplantation given the risk of cancer recurrence or development of second cancer because of therapeutic immunosuppression [19]. If these patients need cardiac transplantation, collaboration with oncologists must occur to assess each patient as to their risk of tumour recurrence. The oncologists evaluated tumour recurrence in the four cases (apart from the patient with pulmonary metastasis) as being low, based on tumour type, response to therapy and negative metastatic workup; therefore, cardiac transplantation was considered after a period of 1–3 years of remission. We successfully transplanted 2 patients with a prior renal cancer after 2 and 3 years of remission, without tumour recurrences after 24 and 22 months from the cancer diagnosis.

The specific waiting time to regain the transplant list after neoplasm remission depends on the tumour type, response to therapy and negative metastatic workup. However, the 5-year remission required to transplant a patient with a history of cancer appears arbitrary [9]. Authors have reported many cases of patients with pre-existing neoplasms undergoing successful cardiac transplantation after 0–2 years without recurrence of the primary tumour [20, 21].

With these cases, we sought to bring new insights in the management of cancer in patients supported with LVAD, the implantation of an LVAD in patients suffering from end-stage heart failure and presenting a malignant tumour allowed us not only to resect the tumour, but also to support the patient until cancer remission and conduct him to regain candidacy list of heart transplantation.

CONCLUSION

Our results suggest that tumour resection in the setting of cancer in a pretransplant candidate under LVAD support can be safely achieved even for high-risk HMI patients, based on rigorous pre-, peri- and postoperative organization. Regaining candidacy for heart transplantation after tumour resection and complete remission is conceivable with the collaboration of oncologists and transplant cardiologists.

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Conflict of interest: Pierre-Yves Litzler is proctor for Thoratec, Inc.

REFERENCES


