An alternative approach to explantation and exchange of the HeartWare left ventricular assist device

Mohammad Sajjad*, Tanveer Butt, Faruk Oezalp, Aleem Siddique, Neil Wrightson, David Crawford, Thasee Pillay and Stephan Schueler

Mechanical Circulatory Support Program, Freeman Hospital, Newcastle upon Tyne Hospitals, NHS Foundation Trust, Newcastle upon Tyne, UK

* Corresponding author. Institute of Transplantation, Freeman Hospital, High Heaton, Newcastle upon Tyne NE7 7DN, UK. Tel: +44-191-2248450; fax: +44-191-2231175; e-mail: jsyousafzai@hotmail.com (M. Sajjad).

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Abstract

OBJECTIVES: Left ventricular assist device (LVAD) explantation and exchange is a relatively infrequent but potentially complex procedure. Patients requiring such procedures have multi-system suboptimal physiological reserve due to end-stage heart failure and are prone to complications. Less-invasive procedures are believed to facilitate postoperative recovery and early mobilization. We describe an alternative approach to explantation and exchange of the HeartWare LVAD through left thoracotomy.

METHODS: Six patients (M = 4, F = 2, mean age = 49.16 years) underwent device explant/exchange or initial implant (explant = 2, exchange = 3, initial implant = 1) through left thoracotomy utilizing cardiopulmonary bypass and induced ventricular fibrillation (VF). The mean bypass time and mean VF arrest time were 82 and 3 min, respectively. A new outflow graft was anastomosed to the previous outflow graft in 3 cases of device exchange and to the descending aorta in 1 case of initial implant.

RESULTS: One patient died in the intensive care unit due to unrelated causes (gram-negative sepsis) after device exchange. All others were discharged alive and currently remain on follow-up. The mean length of hospital stay was 40.66 days.

CONCLUSIONS: On-pump approach through single thoracotomy incision is safe and equally suitable for device explant, exchange and initial implant. However, structural heart defects requiring surgical correction and the requirement of simultaneous right ventricular assist device are the limitations of this approach.

INTRODUCTION

Left ventricular assist devices (LVADs) are being increasingly used for the treatment of end-stage heart failure. Device explantation or exchange is required in cases of myocardial recovery, during heart transplantation or complications, respectively. The myocardial recovery rate of ischaemic or non-ischaemic cardiomyopathy supported with pulsatile or continuous flow LVADs varies significantly and has been reported in the range of 1–60% [1]. In their recent publications, Wu et al. [2], Strueber et al. [3] and Popov et al. [4] reported the 2.83–8% HeartWare device exchange rate for device thrombosis. Redo sternotomy significantly increases the risk of morbidity and mortality [5]. Less-invasive approaches are therefore preferred to minimize the impact of redo surgery and to facilitate postoperative recovery and mobilization. Other authors have described less-invasive approaches [6–8] for device explantation. To avoid redo sternotomy, we are currently exploring an alternative approach to the HeartWare LVAD explantation and exchange through left thoracotomy.

PATIENTS AND METHODS

Patients

Six patients (four males and two females, mean age 49.16 [range 37–60 years]) underwent device explant/exchange or initial implant through single left thoracotomy incision. All cases were performed on Fem–Fem cardiopulmonary bypass and short duration of induced ventricular fibrillation (VF). The device was explanted from 2 patients after myocardial recovery and exchanged in 3 patients due to device thrombosis. Sub-therapeutic anticoagulation due to missed/forgotten medications resulted in device thrombosis in all 3 patients. The mean duration on device support was 479.2 days (range 246–760 days) before exchange/explantation. One patient had initial implant for ischaemic cardiomyopathy. A new outflow graft was anastomosed to the previous outflow graft in 3 cases of device exchange and to the descending aorta in 1 case of initial implant.
Institutional anticoagulation protocol for LVADs

We maintain anticoagulation with warfarin or heparin (fractionated or unfractionated) and one antiplatelet agent (aspirin/clopidogrel/dipyridamole/prasugrel). Our therapeutic range of international normalized ratio (INR) is 2.5–3.5 with a target INR of 2.7.

Platelet inhibition is maintained at >50% and monitored with thromboelastography (TEG). If platelet inhibition on TEG is subtherapeutic, platelet therapy is intensified either by increasing the dose, adding a second antiplatelet agent or by changing to a stronger antiplatelet agent.

Anticoagulation with fractionated heparin infusion is monitored with activated clotting time ranging from 180 to 200 s. In case of unfractionated heparin (tinzaparin), we monitor antifactor Xa levels (therapeutic range 0.50–1.1 U/ml).

Surgical technique

We approach the device for explantation or exchange through single left anterolateral thoracotomy (Fig. 1a). Under general anaesthesia through a double-lumen endotracheal tube, the patient is positioned in the semi-right lateral position. After systemic heparinization, femoral vessels are cannulated for cardiopulmonary bypass. Intraoperative trans-oesophageal echocardiography (TEE) is utilized as part of the routine.

The chest is entered through the left sixth intercostal space between the left para-sternum and the left mid-axillary line. Since the HeartWare LVAD is totally implanted in the pericardial cavity at the LV apex, this approach lands the surgeon directly on the device, which is in contact with the ribs from the inside. Dissection for adhesions, if any, in the pleural cavity is kept to the minimum and focused on access to the device. Minimal dissection under the ribs is performed for placement of the retractor or optimum visualization. Tissue, right on the top of the device, is incised to expose the device and gain entry to the pericardium. Dissection then continues around the device circumferentially to expose the whole device and the sewing ring attached to the LV apex. About 5 cm length of the outflow graft is also freed from the surrounding tissues. Few rings of the protective plastic sleeve around the graft are removed to have a reasonable length for clamping and end-to-end anastomosis with the new graft. Full flow cardiopulmonary bypass is established at this stage and normal body temperature is maintained. The device is switched off and driveline is transected close to the device. Two clamps are applied to the outflow graft, one close to the device and another as distal as possible on the exposed part. The graft is divided between these clamps closer to the device. Ventricular fibrillation is induced and the device is explanted from the LV by loosening the screw at the sewing ring. The sewing ring itself is left in place undisturbed. The LV cavity is inspected and clots, if present, are removed followed by a thorough wash with saline.

Before plugging the hole at the LV apex, thorough de-airing is performed by putting the patient in the Trendelenburg position and letting the LV be filled gradually till all the air is expelled. Additional de-airing, from the ascending aorta, is performed through the stump of the detached outflow graft. After satisfactory de-airing, a custom-made plug (Heart-Plug HeartWare, Steffan Fittkau GmbH, Berlin, Germany) is introduced through the existing sewing ring at the LV apex, while the LV is still being bled through the hole. The screw at the sewing ring, which was loosened earlier for device explantation, is tightened again over the Heart-Plug. In addition, the plug is also secured to the sewing ring with few 4/0 Prolene sutures (Fig. 1b), strictly avoiding suture placement through the viable myocardium. The outflow graft is shortened, then occluded with two layers of sutures and left under the sternum. The intrathoracic part of the driveline is released from the surrounding adhesions and pulled out through a small incision placed directly over the course of the driveline in the anterior abdominal wall. The fabric-covered part of the driveline in the anterior abdominal wall needs one or two small incisions directly on its course to release the surrounding adhesions and should then be removed in segments.

For a device exchange, patency of the existing outflow graft is confirmed after all the necessary dissection is complete and before the faulty device is explanted. It is accomplished by releasing the distal clamp after division of the outflow graft, ensuring free retrograde flow in the graft. The faulty device is now explanted and a new device ‘with the new outflow graft attached’ is then implanted through the existing sewing ring by firmly pushing the inflow cannula of the device through the sewing ring. Lengths of the new and previous outflow grafts are then adjusted for end-to-end anastomosis (Fig. 1c) performed using 4/0 Prolene suture. De-airing of the LV and aortic root is performed through the anastomosis by releasing the clamp on either side of the anastomosis alternately. TEE monitoring is utilized to confirm satisfactory de-airing before final tying. The driveline is placed in the anterior abdominal wall through our standard triple tunnel technique [9] and brought out at its final exit positioned left-lateral to the umbilicus. The semi-right lateral position of the patient allows access to most of the anterior abdominal wall required for this purpose. The patient is weaned off cardiopulmonary bypass, while the device gradually takes over the left-sided circulation. Protamine sulphate is administered; chest drains are placed in the pericardium and in the left pleural cavity. Standard chest closure is then performed.
RESULTS

The mean bypass time and mean VF arrest time were 82 and 3 min, respectively. One patient developed haemotorax after device exchange and needed exploration for evacuation of clots. He later died in the intensive care unit due to gram-negative sepsis. All others were discharged alive. One patient suffered peri-operative embolic stroke with left hemiparesis but recovered completely. Mean length of hospital stay was 40.66 days. This included stay for other reasons such as gastrointestinal bleeding, stabilization of anticoagulation and logistic reasons. Adequate pain control was achieved with patient-controlled analgesia in the immediate postoperative period and with a combination of oral analgesics afterwards. On the verbal pain scale, patients complained of mild pain.

DISCUSSION

Primary device failure, failure of medical therapy for device thrombosis or onset of complications of device thrombosis, such as shock, renal failure, hepatic failure and peripheral embolization, are indications for device exchange. Device explantation, on the other hand, is required after myocardial recovery on device support or during heart transplantation. Recently, published literature [2–4] has reported 2.83–8% HeartWare device exchange rate for device thrombosis. We started implanting the HeartWare LVAD in July 2009 and, so far, in our series of 87 implants we have exchanged 5.74% of these devices for device thrombosis. Keeping in view the complex nature of these procedures, explantation strategies for implantable devices are tailored according to the circumstances and a minimally invasive approach [6–8] is chosen where appropriate. The exchange of device for complications is relatively rare and therefore accumulated experience in this field is limited. To preserve myocardial function, device explantation for myocardial recovery should be performed with the least possible surgical trauma. Similarly, device exchange should also be performed with minimum possible intervention to minimize the impact of surgical trauma and avoid potential complications at the time of device exchange and, subsequently, at the time of transplantation. Redo sternotomy is a complex procedure with an increased risk of perioperative bleeding. Mobilization of the whole heart for apical access should thus be avoided to minimize surgical trauma, perioperative bleeding and transfusion requirements.

Size and design of HeartWare LVAD permit total intrapericardial implantation like a piggy back at the LV apex but not sutured directly to the heart muscle. It is, rather, implanted through a ‘sewing ring’ and secured to it with a small screw. This unique feature allows easier device implant/expant once the ‘sewing ring’ is sutured in place. As a result of cardiomegally due to end-stage heart failure, LV apex is considerably displaced to the left. Therefore, any attempt at HeartWare explantation through redo median sternotomy would be a major undertaking in terms of access. Minimally invasive procedures for device explantation [6–8] play a major role to minimize surgical risk. Other authors have described approaches using multiple incisions and off-pump explantation/implantation of the device [8, 10, 11]; however, experience is limited to case reports or small series. While reasonably minimizing the impact of surgical trauma, an ideal approach should also be safe and easily reproducible. Performing these procedures preferentially under short cardio-pulmonary bypass and VF arrest has several advantages: (i) the entire procedure is performed under controlled situations, (ii) LV cavity can be inspected thoroughly and clots, if any, can be removed, (iii) LV cavity can be washed and sucked up for any sediments of clots, (iv) blood loss is negligible and the procedure is not messy and (v) chances of iatrogenic complications are minimal. In our opinion, the risk of off-pump procedure outweighs the little benefit gained. Furthermore, manipulation of a beating heart may cause arrhythmias, which can be counterproductive in an uncontrolled situation. The custom-made occluding plug (Heart-Plug HeartWare) simplifies device explantation [12] and has other advantages: it (i) is quick, simple and easy to plug the inflow opening, (ii) prevents suture closure of the LV, which is more traumatic, time consuming and less haemostatic and (iii) permits device reimplantation, if needed, at any stage in the future.

During device exchange, new outflow graft anastomosis to the ‘previous outflow graft’, if possible, minimizes the bypass and operating time. If patent, the previous outflow graft should be preferentially utilized to avoid technical difficulties of anastomosis elsewhere. It is therefore essential to confirm patency of the ‘previous outflow graft’ by preoperative computed tomography scan with contrast and intraoperatively by ensuring free retrograde flow after detachment from the device. In case of partial or complete occlusion due to thrombus formation, it is sutured in two layers and abandoned. Retention of a blind limb of previous outflow graft does not warrant an additional procedure for its removal [13]. In this situation, the new outflow graft is anastomosed to the descending aorta in the left chest. Other authors have described tunnelling the outflow graft retrosternally and attaching it to the ascending aorta [11]. But retrosternal tunnelling is safe and possible only in the virgin chest and requires additional incision for anastomosis. Therefore, in patients with previous sternotomies, anastomosis of the outflow graft to the descending aorta is a safer option. There are some concerns regarding increased risk of thrombus formation in the aortic root in patients with outflow graft being anastomosed to the descending aorta [14]. However, the evidence is not compelling and other authors have also reported anastomosis at the descending aorta without any adverse events [15]. Furthermore, the HeartWare LVAD has an aortic root washout mechanism called ‘Lavare Cycle’, which allows the aortic valve to open every 60 s during full support on the device. Therapeutic anticoagulation and antplatelet therapy in combination with washout mechanism probably reduce the risk of aortic root thrombus formation to a very insignificant level.

In rare situations, reimplantation of the device is also possible through the same approach and has been performed by other colleagues for non-sustained myocardial recovery (personal communication—unpublished). After removing the plug, the device is implanted in the usual manner and the outflow graft is attached to the descending aorta. We have performed three device exchanges for device thrombosis, two explants for myocardial recovery and one initial implant for ischaemic cardiomyopathy through this approach. The new outflow graft was anastomosed to the previous outflow graft in the 3 cases of device exchange and to the descending aorta in 1 case of initial implant. One patient died in the intensive care unit due to unrelated causes (gram-negative sepsis) after device exchange. All
others were discharged alive. One patient suffered perioperative embolic stroke with left hemiparesis but recovered completely. We hope that larger data in future will establish more realistic prevalence of mortality and morbidity associated with this approach.

In our opinion, utilization of cardiopulmonary bypass and VF arrest renders safety, keeps the surgeon in control of these complex procedures and has no adverse effect on the outcome. We believe that our on-pump approach through single thoracotomy incision, when compared with multiple incisions by other authors, is safe and equally suitable for device explant, exchange and initial implant. However, acquired or congenital structural heart defects requiring surgical correction and severe right ventricular failure requiring simultaneous right ventricular assist device (RVAD) are the limitations of this approach. We address moderate to severe RV impairment perioperatively through our strict RV management protocol [16] and try to avoid the use of RVAD. If it becomes inevitable, then access strategy is planned accordingly.

Conflict of interest: none declared.

REFERENCES