

Surgical Training Improves Performance in Minimally Invasive Left Ventricular Assist Device Implantation Without Cardiopulmonary Bypass

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OBJECTIVE: We introduced a live animal model for training of minimally invasive implantation of a continuous-flow left ventricular assist device (CF-LVAD) without cardiopulmonary bypass for operator's performance improvement.

DESIGN: After watching a videotape of LVAD implantation on the beating heart through the cardiac apex, the surgical team performed implantation of LVADs into 5 pigs during 3 training sessions in a time series. The procedure success rate, operating time, and technical and global performances by self-evaluation and senior evaluation were compared among the sessions.

SETTING: Animal Experiment Center in Peking University Third Hospital.

PARTICIPANTS: Surgical team comprising a surgical operator, surgical assistant, anesthetist, and scrub nurse performed 3 training sessions in a time series.

RESULTS: The urgent situations requiring proper management were myocardial laceration, massive blood loss, and ventricular arrhythmia induced by hemodynamic instability. After practice, the success rate increased to 100% in session 3. The operating times of session 2 (189.80 ± 14.34 min) and session 3 (149.00 ± 22.85 min) were significantly lower than that of session 1 (262.20 ± 28.26 min). The technical and global performances by self-evaluation and senior evaluation were significantly better in session 3 than session 1.

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CONCLUSION: Simulation training with high-fidelity in vivo model for minimally invasive CF-LVAD implantation improves the surgical team's global performance, success rate, and the ability to manage emergency situations in surgery. (J Surg Ed ■■■■-■■■. © 2017 Published by Elsevier Inc. on behalf of the Association of Program Directors in Surgery)

KEY WORDS: education, ventricular assist device, teaching, surgical procedure

COMPETENCIES: Medical Knowledge, Practice-Based Learning and Improvement

INTRODUCTION

Surgical implantation of a continuous-flow left ventricular assist device (CF-LVAD) via the apex of the left ventricle of a beating heart without cardiopulmonary bypass (CPB) is a minimally invasive yet technically challenging approach. During device implantation, unexpected emergencies such as myocardial laceration, ventricular arrhythmia, massive blood loss, or hemodynamic instability may lead to failure of the procedure. In mainland China, there is currently no commercially available CF-LVAD for clinical use. The HeartMate II (Thoratec Corporation, Pleasanton, CA) and HeartWare HVAD (HeartWare Inc., Framingham, MA) have not been approved by the China Food and Drug Administration for use in patients with end-stage heart failure. Approximately 200 to 250 allogeneic heart transplantations are performed each year because of the shortage of donors,¹ and mechanical circulatory support (MCS) is a promising treatment for end-stage heart failure. Surgical training and certification for LVAD implantation are not

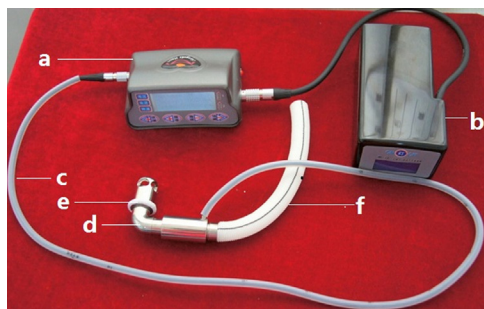


FIGURE 1. CF-LVAD used in simulation training. a: controller; b: extracorporeal battery; c: power line; d: axial flow pump; e: sewing ring; f: outflow graft.

available to cardiac surgeons in China. Without sufficient training and practice, intraoperative emergencies might not be properly managed, potentially leading to a life-threatening crisis. Training and certification for surgical LVAD implantation is essential in China. Surgical training and practice will improve surgical performance and decrease intraoperative emergencies in cardiac surgery. The positive effect of surgical simulation training has been proven in surgical cardiovascular procedures such as the setup of cardiopulmonary bypass,² mitral valve replacement,³ and coronary artery bypass grafting.⁴ In this study, we used a live animal model for surgical training of minimally invasive CF-LVAD implantation without CPB to improve surgical performance and find correct approaches to manage intraoperative crises. If this training program is helpful for performance improvement in LVAD implantation, we will recruit more participants for training and certification in China. This study was approved by the Human Research Ethics Committee and Animal Care and Use Committee of the Third Hospital of Peking University.

MATERIALS AND METHODS

A surgical team comprising a surgical operator, surgical assistant, anesthetist, and scrub nurse participated in the training. Implantation of LVADs through small incisions, avoiding CPB, may decrease activation of the inflammatory and coagulation cascades and decrease bleeding.

After watching a videotape of LVAD implantation on the beating heart through the cardiac apex, the surgical team performed the procedure on live pigs with a continuous axial flow pump developed by a local medical company⁵ (Changzhijuan Medical Development Company, Shanxi, China) (Fig. 1).

TRAINING MODEL

This small pump has a left ventricular apical inflow and a descending aortic outflow and is powered by a percutaneous driveline. The pump is 14 mm in diameter and 40 mm in

length. It weighs 50 g and contains a handmade sewing ring in the input cannula and a $\Phi 12$ mm graft connecting to the output cannula. It provides up to 7 L/min of flow at an output pressure of 100 mmHg when working at 10,000 rpm in vitro.⁵ Pigs with a body weight of 25 to 30 kg were anesthetized and intubated with a tracheal tube. After sterilization and draping, an incision was made anterolaterally in the sixth or seventh left intercostal space. After the ribs had been spread, the left lung was pushed upward to expose the apex of the heart. The pericardium was opened from the apex of the heart along the interventricular groove toward the pulmonary artery root and retracted with stay sutures. Heparin was administered at 3 mg/kg for anticoagulation.

PROCEDURE SIMULATION

Moist gauze was placed in the oblique sinus to elevate the heart. Usually, 6 to 8 pairs of 2-0 pledgeted, braided sutures with double arms (W10B77; Ethicon, Somerville, NJ) were placed around the anatomic apex of the left ventricle in a radiating pattern. The needles were then passed through the sewing ring on the inflow cannula of the LVAD. A 11 blade was used to puncture the apex at the center of the stitches, and a small opening was made with a coring device. The inflow cannula of the LVAD was inserted rapidly in case of massive blood loss. After knotting each pair of sutures on the sewing ring, the descending aorta was exposed, and the $\Phi 12$ mm graft (Vascutek [subsidiary of Terumo UK], Surrey, England) on the outflow cannula of the LVAD was connected to the descending aorta using a 4-0 Prolene suture (Ethicon). Air removal was accomplished by inserting a needle into the outflow graft, and the side clamp on the descending aorta was released. Heparin was neutralized with protamine.

The pump, which was driven by extracorporeal power, started working at 6000 to 8000 rpm to maintain central and peripheral perfusion. The pericardial and skin incisions were closed, and the hemodynamic data were recorded for analysis. A chest drainage tube was left in the pleural space, and antiseptic drugs were used postoperatively.

The surgical team performed 3 teaching sessions with 5 pigs in a time series (session 1 was earliest and session 3 was latest). In session 1, the aforementioned standard technique was used in all 5 animals. In session 2, to manage lethal myocardial laceration and massive blood loss, we surrounded the anatomic apex of the left ventricle with a circular piece of a polyester cardiovascular patch (Qisite Medical Company, Shanghai, China) that was sutured onto the apex of the left ventricle. A mattress suture with double arms was passed first through this polyester patch and deep into the myocardium, then passed out and through the sewing ring of the LVAD. This fixation of each stitch on the tape minimized the possibility of tissue laceration and lethal

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