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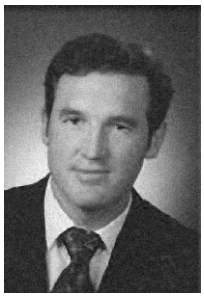
Epicardial Lead Implantation Techniques for Biventricular Pacing via Left Lateral Mini-Thoracotomy, Video-Assisted Thoracoscopy, and Robotic Approach



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ABSTRACT

Purpose: For optimal biventricular pacing, the left ventricular (LV) lead has been found to be best placed in the area where optimal concordance is achieved between the LV pacing site and the site of the most delayed LV wall. For anatomical or technical reasons, the placement of the LV lead via the coronary sinus at the intended target area of the LV is often not possible. An option for avoiding these drawbacks is the surgical implantation of the LV lead under direct vision. This report describes 3 epicardial lead implantation techniques that are less invasive.

Methods: In 80 patients with advanced heart failure and left bundle branch block, epicardial LV leads for biventricular pacing were implanted with 3 different methods: (1) left lateral mini-thoracotomy; (2) a video-assisted thoracoscopy approach using lead implantation tools; and (3) a robotically enhanced telemanipulation system. Video films are provided for all 3 techniques in *The Heart Surgery Forum* online.

Results: Independent of the surgical techniques, the intended lead location on the LV was achieved in all patients. Acute and 3-month LV lead thresholds were satisfactory in 79 patients (99%). Two lead displacements were observed. One thoracotomy was carried out after thoracoscopic lead placement because the patient developed an early exit block. Five patients who underwent an operation with the robot needed a conversion to thoracotomy because of technical failure of the robot (2 patients) or massive pleural adhesions (3 patients). There were no severe adverse events related to any technique. Three patients died in the hospital from the progression of end-stage heart failure.

Conclusion: Epicardial lead implantation for biventricular pacing is feasible with all 3 surgical techniques. Each method allows optimal lead implantation under direct vision and therefore reduces the incidence of nonresponders resulting from suboptimal lead placement.

INTRODUCTION

Large randomized, controlled trials, such as MIRACLE [Abraham 2002] and COMPANION [Bristow 2000, Salukhe 2003], have proven the beneficial effects of biventricular (BiV) pacing, resulting in an increased left ventricular ejection fraction (LVEF), decreased mitral regurgitation, and improved clinical symptoms for patients who have advanced heart failure with left bundle branch block (LBBB). However, the percentage of nonresponders to such therapy has been described as remarkably high at 30% to 50% [Ansalone 2001, Abraham 2002, Auricchio 2002]. The reasons for unchanged or even worsened conditions after BiV pacing often were not stated, but it seems that one of the most important pathophysiological factors may be suboptimal resynchronization therapy [Ansalone 2003]. For anatomical or technical reasons, it is often not possible to place the lead via the coronary sinus and its tributaries to the target area where optimal concordance is achieved between the left ventricular pacing site and the site of most delayed left ventricular wall. In addition, the failure rate and lead-related complications of coronary sinus leads from the time of implantation to 6 months postoperatively have been frequently described to be between 10% and 33% [Purerfellner 2000, Cazeau 2001, Abraham 2002, Fatemi 2003, Young 2003].

An option for avoiding these drawbacks is surgical left ventricular lead placement, which has the advantage of direct access to the lateral left ventricular wall. Direct visualization provides a nearly unrestricted opportunity of lead implantation to the determined optimal target site. The increased morbidity due to extensive sternotomy or thoracotomy [Daoud 2002] is feared by most surgeons. These concerns may not be valid, based on more current surgical technology.

This report describes 3 epicardial lead placement techniques that are less invasive: (1) via a left lateral mini-thoracotomy, (2) via a video-assisted thoracoscopy approach using a lead implantation tool, and (3) with the aid of a robotically enhanced telemanipulation system.

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Table 1. Baseline Characteristics of the Patients*

	Mini-Thoracotomy (n = 16)	Implantation Tool (n = 31)	Robotic System (n = 33)
Male sex, n	9	23	23
Age, y	60.2 ± 9	64 ± 13	66.8 ± 15
NYHA class	3.1 ± 0.6	3.5 ± 0.6	3.2 ± 0.7
Ejection fraction, %	20 ± 7	19 ± 9	25 ± 11
Prior CABG, n	3	9	15
Pulmonary disease, n	3	3	7
Chronic renal insufficiency, n	4	13	4
QRS duration, ms	169 ± 21	ND	172 ± 21
Ischemic cardiomyopathy, n	4	13	10
Previous failed coronary sinus lead, n	11	31	10

*Data presented as the mean ± SD where applicable. NYHA indicates New York Heart Association; CABG, coronary arterial bypass graft; ND, not documented, but all >130 ms.

METHODS

Patient selection was based on the standard BiV pacing criteria: severe congestive heart failure rated as New York Heart Association (NYHA) class III or IV and refractory to optimized pharmacologic heart failure treatment; dilated ischemic or nonischemic cardiomyopathy with left ventricular systolic dysfunction defined by a LVEF <35% and a left ventricular end-diastolic diameter >60 mm; and LBBB as reflected on the surface electrocardiogram by a QRS duration of >120 milliseconds in spontaneous rhythm. All patients gave informed consent to the procedures. The patient demographics are listed in Table 1. The procedures were performed in the operating rooms of 3 cardiothoracic departments: the Department of Cardiac Surgery, University of Munich, Munich, Germany; the Department of Cardiac Surgery, Erasme University Hospital, Brussels, Belgium; and the Division of Cardiothoracic Surgery, Emory University School of Medicine, Atlanta, Georgia, USA.

Mapping for Lead Placement

The optimal left ventricular pacing site was chosen by performing preoperative and intraoperative electrophysiological and hemodynamic measurements and by considering the patient's anatomical conditions. For study reasons, a positron emission tomography scan was performed in 20 patients of the robotic placement group to determine the optimal lead location. Currently, echocardiography with tissue Doppler imaging is most frequently performed in combination with electrophysiological measurements to determine the most delayed site of the left ventricular wall. Anatomically, the leads are placed in most patients just posterior to the obtuse marginal branch of the circumflex artery.

Implantation Procedure

The 3 techniques of surgical epicardial implantation to the left lateral wall of the heart are briefly described below. For each approach, a video is provided in the online publication of *The Heart Surgery Forum*.

The procedures were performed in the operating room with the patient under general anesthesia and beating heart. All patients had standard monitoring (electrocardiography, pulse oxymetry, invasive arterial monitoring, and external defibrillator pads) and a Swan-Ganz catheter if needed. Transesophageal echocardiography was carried out throughout the procedures. For right atrial and right ventricular pacing, transvenous leads were placed in a standard percutaneous, fluoroscopy-guided manner except for 3 patients who underwent thoracoscopic placement of the right ventricular lead. All device pockets were located in the left or right subclavicular space.

I. Mini-Thoracotomy. In the index case (Figure 1), the 40-year-old male patient (dilated cardiomyopathy, 25% LVEF, LBBB >200 milliseconds, NYHA class III) underwent standard single-lumen intubation and was placed in a supine position with the left chest elevated 30 to 40 degrees. Following a 5-cm left lateral, midaxillary mini-thoracotomy at the site of the fourth intercostal space, the left lung was pushed back with a wet towel. The pericardium was opened anterior to the phrenic nerve while a sufficient distance was ensured. The pericardium was fixed with hang sutures to the skin with the heart rotated to the right to create optimal exposure to the lateral surface.

After mapping the left ventricle to determine the optimal pacing location, a unipolar epicardial steroid lead (CapSure Epi Model 4965; Medtronic, Minneapolis, MN, USA) was attached to the target area. Completing the threshold measurements and transesophageal echocardiography assessment, the lead was secured with 2 polypropylene sutures (Prolene 5-0 or 6-0). The connector of the lead was brought through the third intercostal space and submuscularly tunneled to the device pocket and the pacemaker. The pericardium was partially closed. The insertion of a small pleural drain (19F

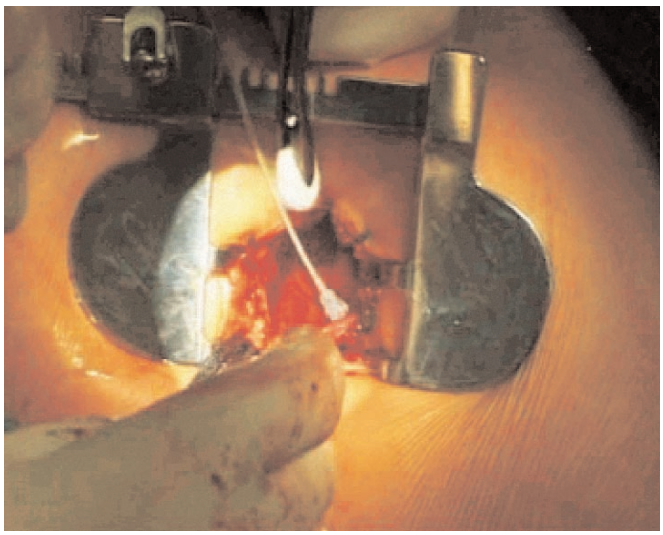

Figure 1. Through a left lateral mini-thoracotomy (5 cm), a unipolar epicardial steroid lead (Medtronic CapSure Epi Model 4965) is stitched on the left lateral wall just posterior to the obtuse marginal branch of the circumflex artery.

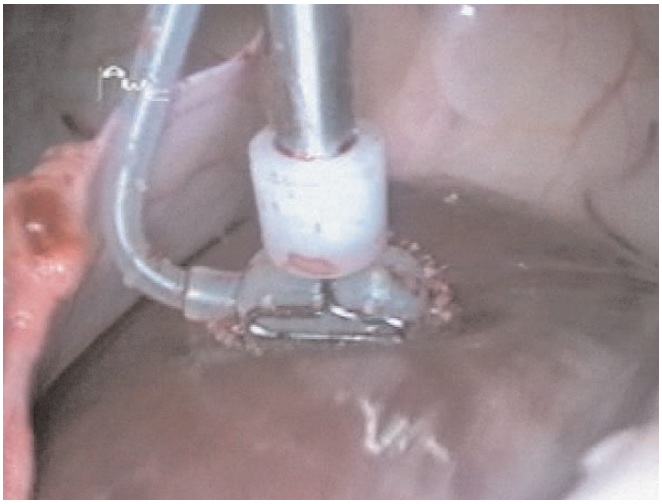

Figure 2. The Medtronic Model 10626 Epicardial Lead Implant Tool with a mounted epicardial screw-in lead (Medtronic Model 5071) is inserted in the chest through a working port (thoracoscopic view).

Blake drain; Ethicon, Norderstedt, Germany) was followed by standard wound closure. The procedure time was 95 minutes. Pacing threshold was excellent (0.3 V/0.5 ms). The amplitude of the R wave was 17.2 mV. One day before surgery, a transvenous implantation of a coronary sinus lead was attempted for more than 5 hours and was abandoned because of dissection of the coronary sinus and a pericardial hematoma of 500 mL.

In 8 cases, bipolar epicardial steroid leads (CapSure Epi Model 4968; Medtronic) were placed. The operation times were prolonged because 2 electrode tips of the lead needed to be fixed and tested separately.

II. Thoracoscopic Approach Using the Medtronic 10626 Epicardial Lead Implant Tool for the Medtronic 5071 Epicardial Pacing Lead. Patients were placed in a supine position with the left chest elevated 45 degrees after a double-lumen endotracheal tube was placed. The left arm was draped below the patient so as not to interfere with tool manipulation during the lead placement. The first port, a 15-mm soft port (primary working port), was placed in the sixth intercostal space at the midaxillary line. The second port, a 5-mm rigid port ("grasping port"), was placed at the sixth intercostal space inferolateral to the left mammilla, and the third port, a 5-mm rigid port (for the endoscope), was placed at the fourth intercostal space in an anterior-axillary line. The pericardium was opened via a 5-cm incision through the second port by tenting the pericardium with a grasper anterior and parallel to the phrenic nerve. If vessels were visible, the pericardial incision was extended, or the edge of the pericardium was elevated until a vessel-free implant site was located. The optimal lead location was defined by mapping.

The Medtronic 10626 Epicardial Lead Implant Tool is the latest of the implantation devices for the Medtronic 5071 Epicardial Pacing Lead. The 5071 screw-in lead was mounted on the proximal end of the malleable implantation tool, and the assembly was inserted in the chest through the 15-mm working port. The lead was carefully placed on the surface of the target area, and gentle pressure was applied (Figure 2). The thumbwheel at the distal end of the implantation tool was turned clockwise 2 complete rotations. Pressing the button at the thumbwheel released the lead, and the insertion tool was removed. A second backup lead was placed posterior to the first one in a similar fashion. If immediate satisfactory pacing threshold was not obtained, the lead was unscrewed with the implantation tool and repositioned to a different site. The lead connectors were tunneled to the previously opened device pocket with one lead connected to the device and the second backup lead capped and buried in the pocket. A thoracotomy drain was placed through one port. The wounds were closed with standard techniques. The latest implantation device, the Model 10626, was used in 8 patients. The other 5071 Epicardial Pacing Leads were placed with the former carrier (stiff shaft).

III. Robotically Enhanced Telemanipulation System. In the index case, the patient was placed in a supine position and tilted 30 degrees to the right. The patient was intubated with a double-lumen endotracheal tube. Three 1-cm port incisions were made in the second, fourth, and seventh intercostal spaces along the left midaxillary line. Two lateral robotic arms and a central 3-dimensional image camera were placed through the ports into the chest. Gentle carbon dioxide insufflation increased the working space between the dilated left heart and the chest wall. The surgeon at the robotic console performed the operation by remotely telemanipulating the endoscopic arms and camera (da Vinci Surgical System; Intuitive Surgical, Mountain View, CA, USA).

Small pericardial incisions were performed with an electrocautery hook to expose the left ventricular lateral wall. Through a fourth lateral 8-mm port (placed in the previously made pocket for the pacing device), the lead was positioned under direct vision. The lead was passed into the first (proximal) pericardial incision and brought to the second (distal) incision, which was the presumed stimulation site. This "pericardial bridge" was made to secure the trajectory of the distal electrode. The lead was kept carefully at the target location of the epicardium, and threshold measurements and an echocardiographic assessment of resynchronization efficiency were made. The probe was held in contact with the lateral wall and was stitched to the adjacent pericardium with 4-0 polyester (Ticron) suture (Figure 3). The connector of the lead was brought through the second intercostal space to the stimulator in a left pectoral pocket.

The leads used were conventional unipolar or bipolar epicardial electrodes (CapSure Epi Models 4965 or 4968) in most cases. In 8 cases, a special modified lead, the "shark fin" lead, was used (Figure 3). This prototype was developed by the Bakken Research Center, Medtronic, Maastricht, the Netherlands, on special request. On the back of the electrode tip, a 4-mm silicon top (the shark fin) was mounted for advanced intrathoracic handling.

RESULTS

All 80 patients had an optimal epicardial lead placement at the determined target area that was independent of the surgical tech-

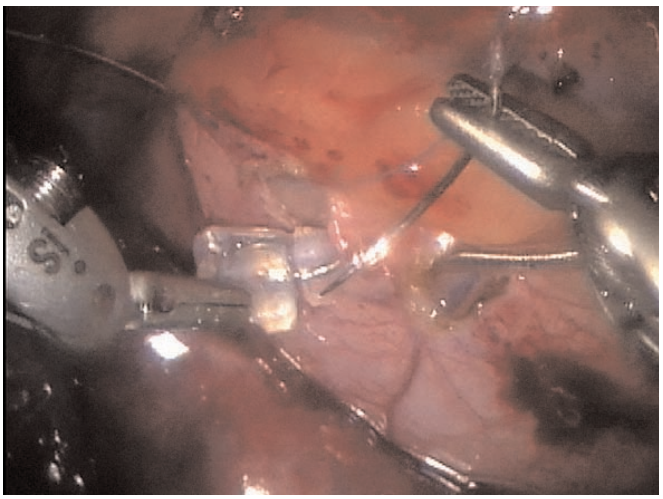

Figure 3. da Vinci robotic system, thoracoscopic view. The "shark fin" lead (modified Medtronic Model 4965) is held with the left robotic tool (SI) at the fin mounted on the lead tip and kept in contact with the lateral wall during the stitching of the electrode.

nique used (Table 2). Electrophysiological controls revealed excellent acute and 3-month follow-up results. All operation times (skin to skin, including endocardial lead placement) were of reasonable length, and the operation times were independent of the technique used. These times also included the times for sterile draping and calibration when the implantation was performed with the robotic system. The "endoscopic" robotic time for pericardial opening and lead fixation was 20.6 ± 5.2 minutes. For the shark-fin lead tip only, the robotic time was reduced to 18.3 ± 4.4 minutes. Because of the small numbers of shark-fin lead implantations, this shorter time did not reach statistical significance. With the latest Medtronic implantation tool, the Model 10626 with its malleable shaft, used for the thoracoscopic approach, the total operation time (skin to skin) was reduced from 180 minutes to almost 60 minutes. The time for lead placement with the 10626 device itself was not measured, but it took only a few minutes. The most time-consuming element was the thoracoscopic exposure of the left ventricular target area. Eight patients in the mini-thoracotomy group received bipolar leads, the installation of which vastly increased the average lead-positioning time.

Three patients did not clinically respond to BiV pacing. We observed no major adverse events related to any implantation procedure (Table 3). In the mini-thoracotomy group, 2 patients developed a pneumothorax after the operation, but no operative intervention was necessary. During intubation for the surgical lead placement via mini-thoracotomy, 1 patient experienced an occluded upper lobe of the right lung; thus, the operation had to be postponed 4 days. One patient with mini-thoracotomy access experienced a lead displacement. The same patient (progressive end-stage heart failure, NYHA class IV, mitral valve insufficiency class IV) died in the hospital from progressive heart failure. Prior to lead implantation in this patient, a mitral valve operation was refused because of his bad clinical condition.

After lead placement with epicardial implantation tool 10626, 2 patients developed a pneumothorax that was successfully treated with drains. Two other patients who were receiving warfarin therapy required transfusion. One patient (ischemic end-stage heart failure and previous coronary artery bypass grafting) experienced an exit block. A second thoracoscopic attempt and the subsequent thoracotomy in this patient failed, both because of repeated exit block. At a later stage, this patient died of multiorgan failure.

In the robotically treated group, 5 patients underwent conversion to thoracotomy. Three patients underwent conversion for anatomical reasons (adhesions), and in 2 procedures the robot had to be removed because of technical failure. Three of the patients who needed conversion were postoperatively treated with antibiotics for pneumonia. One patient (a 72-year-old man with ischemic end-stage heart failure) with renal failure requiring dialyses died 3 weeks postoperatively. Four days after initial recovery from the operation, this patient developed acute respiratory distress syndrome.

DISCUSSION

The results of the described implantation techniques indicate a broad improvement toward optimal left ventricular lead

Table 2. Intraoperative Data and 3-Month Follow-up*

	Mini-Thoracotomy	Implantation Tool	Robotic System
Procedure time, min	134 ± 38	65-180†	136 ± 48
Acute threshold, V/0.5 ms	1.1 ± 0.6	1.6 ± 0.2	1.2 ± 0.3
Acute R-wave amplitude, mV	13.6 ± 8.0	9.6 ± 1.0	14 ± 1.6
Threshold at 3 mo, V/0.5 ms	0.8 ± 0.3	ND	1.9 ± 0.6
R wave amplitlude at 3 mo, V/0.5 ms	11 ± 6	ND	10 ± 1.8
Optimal lead location, n (%)	16 (100)	31 (100)	33 (100)

*Data presented as the mean ± SD where applicable. ND indicates not documented.

†In 8 cases, the latest modification of the implant tool, Model 10626, was used. The average time of the procedure decreased with this tool's adoption and the surgeons' maturing experience from 3 h to almost .5 h.

Table 3. Adverse Events

	Mini-Thoracotomy	Implantation Tool	Robotic System
Lead dislodgment or exit block, n	1	1	1
Nonresponder, n	1	1	0
Conversion to thoracotomy, n	—	1	5
Implantation-related major adverse events, n	0	0	0
Implantation-related minor adverse events, n	3	4	3
Postoperative intubation >24 h, n	2	3	1
Early mortality, n	1	1	1
Number of patients who experienced adverse events	4	5	6

placement and cardiac resynchronization therapy with BiV pacing. We observed only a few implantation-related adverse events and a low mortality rate. Compared with the adverse events and failure rates observed with the transvenous approach [Purerfellner 2000, Cazeau 2001, Abraham 2002, Fatemi 2003, Young 2003], such as dissection or perforation of the coronary sinus, unsuccessful lead implantation, muscle or phrenic nerve stimulation, lead displacement, and loss of pacing capture, these surgical procedures emerge as an excellent alternative.

Current views of the surgical approach to resynchronization therapy vary from center to center, but in most places, it is considered a therapy of last resort or not even an option. This situation has resulted in time-consuming and cost-intensive transvenous attempts and, often, implantation of the coronary sinus lead in atypical sites, eg, the anterior or middle cardiac vein. Therefore, many patients do not receive the best therapy and end up with only suboptimal dual-chamber pacing or as nonresponders to BiV pacing [Cazeau 2001, Abraham 2002, Auricchio 2002, Young 2003]. In our centers, epicardial lead placement has proven to be a feasible treatment option and is now considered an equivalent therapy or the second choice if the optimal pacing site is not attainable with the transvenous approach within a reasonable time.

A nonresponse to BiV pacing may also occur with surgical epicardial lead placement, but it is not due to the implantation technique itself, because it has been demonstrated that all target areas can be reached. Inadequate mapping techniques prior or during surgery may be the cause. Therefore, it is most important to understand the complex pathophysiology of the LBBB and the failing heart [Ansalone 2003]. Furthermore, other factors, such as large ischemic areas of the left lateral wall or additional mechanical dysfunction for any reason, may play roles in reducing BiV pacing effectiveness.

Different approaches to placing the left ventricular lead, including thoracotomy, robotics, and thoracoscopic placement are viable, and each approach has its advantages and disadvantages. The mini-thoracotomy offers some advantages in that special operation equipment is not mandatory and the operation can be performed in nearly every surgical unit. However, the smaller incision makes a higher demand on surgical expertise. Compared with the thoracoscopic approaches, one drawback of thoracotomy may be the postoperative pain caused by the rib retraction. Daoud and colleagues [Daoud 2002] described a relatively high morbidity and mortality rate within their thoracotomy group; however, the 43% mortality rate was associated with the absence of spironolactone therapy, once again demonstrating that patients referred for surgery, especially those with advanced heart failure, need optimized perioperative drug therapy to gain an optimal postoperative outcome. This is in favor of epicardial lead placement, because many patients in our groups had undergone long-lasting surgical attempts to place coronary sinus leads with the use of contrast fluid and a flat supine position prior to surgery, which also encumbers the failing heart. This might have had effects on our postoperative results as well.

In the past, the medical device industry concentrated their efforts on developing transvenous leads, but because of the fairly high number of nonresponders and the failure rate of coronary sinus leads, the interest in improving surgical methods is growing. The malleable Model 10626 Epicardial Lead Implant Tool launched recently by Medtronic [Medtronic 2003] provides great access flexibility to nearly every site of the heart, especially to the lateral and posterior walls. Moreover, a minimally invasive thoracoscopic approach is possible, and intraoperative trauma is therefore reduced without compromising optimal lead placement. Nevertheless, the thoracoscopic approach has had its learning curve, and the initial difficulty level was moderate to high, especially with earlier models of the lead placement device. Improved experience and the flexibility of the new device have made access to all regions of the heart easier and faster. In implementing the use of such tools, we recommend starting with a mini-thoracotomy approach but using the endoscope as well. So far, the long-term results regarding the threshold and durability of the 5071 leads implanted on the left ventricle in adults are not available. Because the 5071 lead is a screw-in electrode, there may be a potential risk of exit block and reduced longevity. Hence, a second backup lead was placed in this series of patients to prevent them from having to undergo an early reoperation. Further advances and new prototypes for the next generation of epicardial leads are already in development.

In the robotically assisted series, stitch-on leads (the CapSure Epi unipolar 4965 or bipolar 4968) were used. These steroid-eluting electrodes have proven in long-term follow-up studies to be efficient [Beaufort-Krol 1999]. The shark-fin modification enables very comfortable handling without the need to touch the active part of the lead tip. Screw-in electrodes have not been used, because the long-term threshold may be uncertain [Sachweh 2000].

In the Brussels center [Jansens 2003], the robotic approach is the therapy of choice for cardiac resynchronization. The overall success rate was convincing. The debatable drawback of the robotic procedure is its cost-effectiveness compared with the transvenous approach. The robotic operation is performed by a single surgeon and a scrub nurse at the patient's side and requires simple robotic tools at a supplementary cost of 700 Euros, notwithstanding the capital equipment cost of the robotic system. Cost-effectiveness will be an important determinant in the adoption of this technique, and limited access to robotic systems may hamper the widespread use of this technique.

CONCLUSION

Epicardial lead implantation for BiV pacing is feasible with all 3 surgical techniques. Each method allows optimal lead implantation under direct vision and therefore reduces the incidence of nonresponders due to anatomical or technical reasons. We suggest the mini-thoracotomy as an appropriate solution to a suboptimal or time-consuming transvenous left ventricular lead placement. Thoracoscopic approaches with further improvements in the leads and implantation devices are at least equivalent or possibly better treatment options than the coronary sinus approach for BiV pacing.

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